# State Operations Manual

## Chapter 5 - Complaint Procedures

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**(Rev. 1, 05-21-04)**

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## 5000 - Management of Complaints and Incidents

**(Rev. 1, 05-21-04)**

The following procedures provide direction and guidance in the management of complaints and reported incidents for nursing homes, home health agencies, end-stage renal disease facilities, hospitals, suppliers of portable x-ray services, providers of outpatient physical therapy or speech pathology services, rural health clinics, and comprehensive outpatient rehabilitation facilities.

For these providers, the management of complaints and reported incidents is supported by the national implementation of the ASPEN Complaints/Incidents Tracking System (ACTS).

Sections 5000 to 5060 supercede §§5100 to 5590, where inconsistencies may exist.

## 5010 - Intake Process

**(Rev. 1, 05-21-04)**

An allegation is an assertion of improper care or treatment against a Medicare, Medicaid or CLIA participating program that could result in the citation of a Federal deficiency. The point of receipt of the allegation is a critical fact-finding and decision-making point. Information regarding the care, treatment and services provided to beneficiaries can come from a variety of sources and in a number of formats. Allegations may come directly from beneficiaries themselves, beneficiaries' family members, health care providers, concerned citizens, public agencies, or in published or broadcast media reports. Report sources may be verbal or written. In some instances, the complainant may request anonymity.

The SA and RO ensure the privacy and anonymity of every complainant. Generally, the SA follows the disclosure procedures under §3308. The SA discloses the complainant's identity only to those individuals with a need to know who are acting in an official capacity to investigate the complaint.

In addition to these Federal requirements, the SA abides by any State procedures not in direct conflict with CMS instructions. The SA notifies the RO if State regulations conflict directly with any part of these complaint procedures.

## 5010A - Information to Collect From Complainant

**(Rev. 1, 05-21-04)**

To the extent possible, the SA captures complete information necessary to make important decisions about the allegations. In instances where written allegations are received, either subsequent verbal and/or written communication may be necessary to

obtain comprehensive information. In the case of allegations received verbally (telephone or face-to-face meetings), an important opportunity exists to obtain complete information to assist with the decision-making and investigative processes.

Comprehensive information should be collected during the intake process to allow for proper triage to occur. This information includes the following:

- Information about the complainant (e.g., name, address, telephone, etc.);
- Individuals involved and affected, witnesses and accusers;
- Allegation category (ies) (e.g., abuse, neglect, dietary, nursing services, etc.);
- Narrative/specifics of the allegation including the date and time of the allegation;
- The complainant's views about the frequency and pervasiveness of the allegation;
- Name of the provider/supplier including location (e.g. unit, room, floor) of the allegation, if applicable;
- How/why the complainant believes the allegation occurred;
- Whether the complainant initiated other courses of action, such as reporting to other agencies, discussing issues with the provider, and obtaining a response/resolution; and
- The complainant's expectation/desire for resolution/remedy, if appropriate.

## 5010B - Information to Provide to Complainant

**(Rev. 1, 05-21-04)**

An effective complaint intake process provides information to assist the complainant in resolving his/her conflicts. The information provided to the complainant may be communicated verbally during initial or subsequent telephone discussions or through written correspondence when acknowledging receipt of the allegation. In either case, the following elements, at a minimum, are provided as part of the intake:

- The SA's policies and procedures for handling intakes including the scope of the SA's regulatory authority and any considerations pertaining to confidentiality;
- The course of action that the SA or RO will take and the anticipated time frames;
- Information about other appropriate agencies that could provide assistance including the name and telephone number of a contact person, if available; and

- An SA contact name and number for follow-up by the complainant.

## 5020 - Triage and Priority Assignment

**(Rev. 1, 05-21-04)**

A complaint is a report made to the SA or RO by anyone other than the administrator or authorized official for a provider or supplier that alleges noncompliance with Federal and/or State laws and regulations. If, based on the intake information received, the SA determines that the allegation(s) falls within the authority of the SA, the SA determines the severity and urgency of the allegations, so that appropriate and timely action can be pursued. Each SA is expected to have written policies and procedures to ensure that the appropriate response is taken for each complaint. This structure needs to include response time lines and an orderly process to document actions taken by the SA in responding to every allegation. If a State's time frames for the investigation of a complaint/incident are more stringent than the Federal time frames, the intake is prioritized using the State's time frames. The SA is expected to be able to share the logic and rationale that was utilized in triaging the allegation for investigation. The SA response must be designed to protect the health and safety of all residents, patients and clients.

An assessment of each intake must be made by an individual who is professionally qualified to evaluate the nature of the problem based upon his/her knowledge of current clinical standards of practice and Federal requirements. In situations where a determination is made that immediate jeopardy may be present and ongoing, the SA is required to investigate within two working days of receipt of the information. For all non-immediate jeopardy situations, the complaint/incident is to be prioritized within two working days of its receipt, unless there are extenuating circumstances that impede the collection of relevant information. There are circumstances when a provider/supplier is required to report information to the SA. This is defined as an incident - an official notification to the SA or RO from a self-reporting provider or supplier (i.e., the administrator or authorized official for the provider or supplier), or from a separate agency that is providing information about a provider or supplier. The reported incident intake is prioritized after sufficient information is gathered and evaluated. The SA response is expected to protect the health and safety of all residents, patients and clients.

An investigation is a review to determine if a deficient practice is or was present, and to assess the degree of harm to any resident(s), patient(s) or client(s). To assist in planning the investigation, the SA reviews any information about the provider that would be helpful to know. This may include the provider's compliance history, the provider's quality indicators, or supporting information received from other programs such as the ombudsman program or protection and advocacy program. This process may require additional contact with the complainant. For non-deemed providers and suppliers, CMS expects the SA to investigate allegations of violations of the Federal participation requirements.

For deemed providers and suppliers, if the SA receives a substantial allegation of noncompliance, an appropriate investigation is initiated, if one is warranted, once RO approval has been obtained. (In 1997 CMS, then HCFA, issued "Guidelines for Complaint Investigation." These guidelines continue to serve as a generic, supplementary document to assist SAs with investigative protocols.)

Generally, allegations about nonrecurring events that occurred more than 12 months prior to the intake date will not require the SA to conduct an investigation. However, the SA is not precluded from conducting an investigation to determine current compliance status based on concerns identified during the intake or triage process. More specifically for nursing homes, if there is sufficient evidence that the facility does not have continuing noncompliance, as evidenced by a systemic problem, and the intake reported relates to an event that occurred before the last standard survey, an onsite survey may not be required.

Complaint investigations should not normally impact upon Medicare/Medicaid certification survey schedules. Complaint visits usually occur between regular, full surveys and focus on a specific problem area only. However, if there are potential efficiencies in combining complaint and certification surveys and/or advancing the certification visit date without sacrificing the integrity of either, the SA should do so.

Additionally, the SA considers facilities for more frequent surveys when they present significant compliance problems because of frequent complaints or non-credible POCs.

## 5030 - Priority Definitions

**(Rev. 1, 05-21-04)**

## 5030A - Immediate Jeopardy

**(Rev. 1, 05-21-04)**

The regulations at 42 CFR 489.3 define immediate jeopardy as, "A situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." Intakes are assigned this priority if the intake information indicates immediate corrective action is necessary because a provider's or supplier's alleged noncompliance with one or more conditions or requirements may have caused, or is likely to cause, serious injury, harm, impairment or death to a resident, patient or client. Immediate jeopardy and serious and immediate threat are interchangeable terms.

In situations where a determination is made that immediate jeopardy may be present and ongoing, the SA is required to investigate within two working days of receipt of the information except: (1) For all Medicare deemed providers/suppliers complaint and incident intakes, the SA investigates a complaint within two working days of receipt of the Form CMS-2802, "Request for Validation of Accreditation Survey," from the RO if the RO determines that the complaint involves potential immediate jeopardy to patient

health and safety; (2) For hospital EMTALA complaints, the investigation is completed within five working days after receipt of the authorization from the RO; (3) For restraint/seclusion death reports, the SA completes the investigation within five working days of receipt of telephone authorization from the RO. (Appendix Q contains the Guidelines for Determining Immediate Jeopardy.)

## 5030B - Non-Immediate Jeopardy - High

**(Rev. 1, 05-21-04)**

A priority of non-immediate jeopardy - high is defined as harm that impairs mental, physical and/or psychosocial status. Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions may have caused harm that negatively impacts the individual's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. Usually, specific rather than general information (such as, descriptive identifiers, individual names, date/time/location of occurrence, description of harm, etc.) factors into the assignment of this level of priority.

Regarding allegations pertaining to residents in nursing homes, if the SA makes the determination that a higher level of actual harm may be present, the investigation is to be initiated within 10 working days of its receipt. The initiation of these types of investigations is generally defined as the SA beginning an onsite survey. It is often difficult to distinguish between those allegations that would require an investigation within two working days (immediate jeopardy) from those that would require an investigation within 10 working days (higher level of actual harm). The following are some examples of allegations that indicate that a higher level of actual harm may be present:

- Resident is intimidated/threatened;
- Resident is physically abused - spitting/slapping/sticking with sharp object/pushing/pinching;
- Unexplained/unexpected death, with circumstances indicating that there was abuse or neglect;
- Sexual assault/sexual harassment/coercion;
- Falls resulting in fracture (e.g., handrails not secured);
- Inappropriate use of restraints resulting in injury;
- Inadequate staffing which negatively impacts on resident health and safety; and

- Failure to obtain appropriate care or medical intervention, i.e., failure to respond to a significant change in the resident's condition.

Attachment 1 describes examples to assist the SAs in distinguishing between the priorities of "immediate jeopardy" and "non-immediate jeopardy - high."

## 5030C - Non-Immediate Jeopardy - Medium

**(Rev. 1, 05-21-04)**

A priority of non-immediate jeopardy - medium is defined as harm or potential of more than minimal harm that does not significantly impair mental, physical and/or psychosocial status. Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions has caused or may cause harm that is of limited consequence and does not significantly impair the individual's mental, physical and/or psychosocial status to function. An onsite survey should be scheduled to review these intakes.

Non-EMTALA, and non-immediate jeopardy complaints for providers/suppliers with deemed status require an onsite survey within 45 calendar days after approval by the RO.

## 5030D - Non-Immediate Jeopardy - Low

**(Rev. 1, 05-21-04)**

A priority of non-immediate jeopardy - low is defined as discomfort. Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage. An onsite investigation may not be scheduled, but the allegation would be reviewed at the next onsite survey.

## 5030E - Administrative Review/Offsite Investigation

**(Rev. 1, 05-21-04)**

This priority is used for complaint and incident intakes triaged as not needing an onsite investigation. However, further investigative action (written/verbal communication or documentation) initiated by the SA or RO to the provider is gathered and the additional information is adequate in scope and depth to determine that an onsite investigation is not necessary; however, the SA has the discretion to review the information at the next onsite survey.

## 5030F - Referral - Immediate

**(Rev. 1, 05-21-04)**

Complaints/incidents are assigned this priority if the seriousness of a complaint/incident and/or State procedures requires referral or reporting to another agency, board, or network **without delay** for investigation.

## 5030G - Referral - Other

**(Rev. 1, 05-21-04)**

Complaints/incidents assigned this priority indicate referral to another agency, board, or network for investigation or for informational purposes.

When the SA refers the complaint to another agency or entity (e.g., law enforcement, Ombudsman, licensure agency, etc.) for action, the SA must request a written report on the results of the investigation. Regardless of who conducts the investigation, the SA has the responsibility to assess the provider's or supplier's compliance with Federal conditions or requirements and the time frames for investigation are not altered by the referral to another agency. (Expressed requests by law enforcement that the SA defer an onsite investigation would be discussed with the CMS RO, as appropriate.)

## 5030H - No Action Necessary

**(Rev. 1, 05-21-04)**

Adequate information has been received about the complaint or incident intake such that the SA can determine with certainty that no further investigation, analysis, or action is necessary.

For all cases except EMTALA, that do not allege immediate jeopardy, and at the SAs discretion an intake may not require a new onsite investigation if, at a previously completed survey, the same events were investigated; the previously completed survey evaluated the appropriate individuals, including those identified in the intake; and the situation did not worsen.

## 5040 - Investigation Findings and Reports

**(Rev. 1, 05-21-04)**

Each SA establishes reporting policies, procedures and formats including report language targeted to specific audiences. The SA/RO provides the complainant and the investigated provider a written report of the investigation findings as a summary record of the investigation.

The following principles guide preparation of the report to the complainant:

- Acknowledge the complainant's concern(s);

- Identify the SA's regulatory authority to investigate the complaint/incident and any statutory or regulatory limits that may bear on the authority to conduct an investigation;

- Provide a summary of investigation methods (e.g., on-site visit, written correspondence, telephone inquiries, etc.);

- Provide date(s) of investigation;

- Provide an explanation of your SA's decision-making process including definitions of terms used (i.e., substantiated or validated, unsubstantiated or not validated, etc.);

- Provide a summary of your SA's finding.

  (**NOTE**: To the extent possible the summary should not compromise the anonymity of individuals, or include specific situations that may be used to identify individuals, when anonymity has been requested or is appropriate in the judgment of the SA);

- Identify follow-up action, if any, to be taken by your agency (i.e., follow-up visit, plan of correction review, no further action, etc.); and

- Identify appropriate referral information (i.e., other agencies that may be involved).

## 5050 - CMS Regional Office Responsibility for Monitoring SA Management of Complaints and Incidents

**(Rev. 1, 05-21-04)**

CMS ROs are responsible for monitoring the SAs' management of complaints and incidents to assure that the SAs are complying with the provisions set forth in Federal regulations, the SOM, and CMS policy memoranda. As part of the monitoring process, the SAs will be evaluated in accordance with the criteria set forth by the State Performance Standard Review. Many States have State laws and regulations that specify how to manage complaints and incidents. Whenever possible, State and Federal requirements should be integrated to avoid unnecessary duplication. CMS ROs should accept State requirements that meet or exceed the intent of the Federal requirements. However, at a minimum, it is expected that noncompliance with Federal requirements resulting from a complaint or reported incident will receive follow-up and be documented in ACTS.

# 5060 - Aspen Complaints/Incidents Tracking System (ACTS)

**(Rev. 1, 05-21-04)**

The ASPEN Complaints/Incidents Tracking System (ACTS) is a windows-based program designed to track, process, and report on complaints and incidents reported against health care providers and suppliers regulated by CMS. It is designed to manage all operations associated with complaint/incident processing, from initial intake and investigation through the final disposition.

ACTS must be used for the intake of all allegations for skilled nursing facilities, nursing facilities, home health agencies, end stage renal disease facilities, hospitals, suppliers of portable x-ray services, providers of outpatient physical therapy or speech pathology services, rural health clinics, and comprehensive outpatient rehabilitation facilities. ACTS is a Federal system and data entered into ACTS is subject to Federal laws governing disclosure and the protection of an individual's right to privacy.

## 1 - Data Entry

The SAs and ROs are required to enter into ACTS:

- All complaint information gathered as part of the SA survey and certification responsibilities as set forth in the§1864 Agreement, regardless if an onsite survey is conducted; ***and***

- All reported incident information gathered as part of the SA survey and certification responsibilities as set forth in the §1864 Agreement **and** requires an onsite survey.

The information is entered into ACTS regardless of the entity within a State carrying out this function. The information recorded in ACTS reflects the facts furnished by the complainant at the time of the intake. If the intake information requires an onsite survey and the allegation may involve both Federal and State licensure requirements, a Federal onsite survey is completed and entered into ACTS, at a minimum.

Where an investigation finds one or more violations of Federal requirements, the findings must be cited under the appropriate tags and entered into the Federal system even if the information is entered into a State licensure system. Since this information is essential to the effective management of the survey and certification program, it is important that SAs complete the required fields in ACTS in a timely manner.

Attachment 2 defines the required fields in ACTS.

**2 - Reports**

ACTS produces a variety of reports that may be used for analysis and evaluation of provider/supplier performance. Complaint/incident reports are generated and displayed through menus that can be accessed in ACTS. Reports may be produced for one provider/supplier, or reports may combine and present information from multiple providers/suppliers. Report filtering criteria is available through the Report Customization window, which allows the user to select criteria for the report to meet the user's specifications. Refer to the *ACTS Procedures Guide* for a list and description of the reports available in ACTS.

## 5100 - Investigation of Complaints Against Accredited/Deemed Providers and Suppliers

**(Rev. 1, 05-21-04)**

**SOM 3260 - 3276**

Before the SA conducts a complaint investigation survey against an accredited hospital or deemed provider/supplier, it must receive authorization from the RO. It is the RO's responsibility to determine whether the complaint alleges one or more Condition-levels of non-compliance. If the complaint identifies one or more Condition-levels of non-compliance, the RO must authorize the complaint investigation by completing the applicable Form CMS-2802. If the RO does not authorize the complaint investigation, the SA may conduct a complaint investigation should it determine that the accredited hospital or deemed provider/supplier is non-compliant with its State regulations (i.e., State licensure laws). RO authorization is not required when the SA's basis for conducting the complaint investigation is related to a State regulation.

The RO must complete the Form CMS-2802 in ACTS even if the SA received an initial verbal authorization from the RO to initiate the complaint validation survey of a deemed provider/supplier. Since ACTS allows the RO to authorize a complaint validation survey electronically by completing the RO Signature box on the deemed tab, it is not required to send a signed hard copy of the Form CMS-2802 to the SA via fax or U.S. Postal Service. Once the SA receives the authorization through ACTS it may begin its complaint investigation of an accredited hospital or deemed provider/supplier. Whether the survey is of one or all Medicare conditions, it will be treated as a complaint survey under ACTS rather than a re-certification survey, since the complaint is the basis for the survey.

# 5110 - Basis for Investigation of Complaints Against Accredited/Deemed Providers and Suppliers

**(Rev. 1, 05-21-04)**

**SOM 3260**

Sections 1864(c) and 1865 of the Social Security Act (the Act) provides the basis for conducting complaint surveys of accredited hospitals and establishes the basic framework for conducting complaint surveys for virtually all other deemed providers or suppliers. Regulations authorizing such surveys are found in 42 CFR 488.7(a)(2). The State survey agency (SA) should refer to the CMS Regional Office (RO) all allegations against the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) accredited hospitals concerning violations of 42 CFR 489.24 or the related provisions of 42 CFR 489.20, "Responsibilities of Medicare Participating Hospitals in Emergency Cases." The SAs should also report poor quality of care to the RO, or other indications of noncompliance with the Conditions of Participation (COP). Entities and facilities that are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) are responsible for meeting the CLIA conditions and requirements under 42 CFR Part 493.

A substantial allegation of noncompliance refers to a complaint from any of a variety of sources, including complaints submitted in person, by telephone, through written correspondence, or in news media articles, that, if substantiated, would have an impact on the health and safety of patients, and that raises doubts as to a provider's or supplier's compliance with one or more of the COP or CfC.

If the RO learns of a substantial allegation of noncompliance concerning an accredited hospital or deemed provider/supplier, it will review the complaint, to determine if the complaint identifies the provider/supplier noncompliance with one or more of the Medicare Conditions. If the RO identifies potential noncompliance, it will refer the complaint to the SA for investigation or it will conduct its own investigation. If an allegation was received formally by the RO, the RO is responsible for sending the complainant a complaint receipt letter. This letter acknowledges the receipt of the complaint and advises the complainant that an appropriate investigation will be initiated. In addition, the RO is responsible for sending the complainant follow-up letters. These letters may include information regarding the results of the complaint investigation and may advise the complainant, of any corrective action taken against the provider/supplier.

If the SA receives a substantial allegation of noncompliance directly from a complainant regarding an accredited hospital or deemed provider/supplier, it acknowledges receipt of the complaint, and advises the complainant that an appropriate investigation will be initiated if one is warranted. In this instance, the RO is not responsible for sending the complainant a complaint receipt letter. The SA forwards a copy of the acknowledgment letter and the complaint to the RO. The SA may not conduct a complaint survey for an accredited hospital or deemed provider/supplier unless it is authorized by the RO. The

RO is responsible for determining whether the complaint identifies an allegation of Medicare noncompliance. If the RO determines that the complaint does not warrant an investigation by the SA, it must send a copy of the complaint allegation to the appropriate accreditation organization if the allegation pertained to any survey or enforcement issues.

If the RO does not authorize the complaint survey, the SA may have authority through State law or some other authority to pursue some aspects of the allegations on its own. However, the SA should advise the RO prior to instituting any State action against an accredited hospital or deemed provider/supplier. The SA should ensure that the complaint and pertinent copies of its State initiated survey investigation report are submitted to the RO.

If the SA or RO determines that a complaint refers to a question or issue that is clearly beyond the purview of the Medicare survey and enforcement program, the SA should advise the complainant of the limits of the SA or RO involvement and, if appropriate, suggest a possible alternative source of assistance, or refer the complaint to the appropriate agency.

## 5120 - RO Direction of Accredited Hospital Complaint Investigation

**(Rev. 1, 05-21-04)**

**SOM 3262**

If the RO determines that a complaint investigation survey should be performed, the RO completes the applicable Form CMS-2802, "Request for Validation of Accreditation Survey," (See Exhibit 33), and forwards it to the SA. The RO must complete Item 7 of Form CMS-2802 to identify the Conditions to be investigated by the SA. The RO may, in addition, identify other related areas for SA review during the survey. When an investigation can be conducted by letter or telephone, such as for verifying personnel credentials, those means are to be used. The RO may direct the SA to investigate specific areas of the hospital's operation related to the anti-dumping provisions where there is an indication of noncompliance with 42 CFR 489.24, the related requirements of 42 CFR 489.20, and/or a COP. The SA has responsibility to investigate whether the regulations are violated and/or whether the Conditions in question are met.

The SA uses the appropriate methods for documenting and summarizes each allegation identified in the complaint. Form CMS-562 (Exhibit 75) is not intended for this purpose. If the RO determines that the complaint involves the potential of immediate jeopardy to patient health and safety, the SA must investigate the complaint within two working days of receipt of the signed Form CMS-2802. The RO completes the appropriate Form CMS-2802, which authorizes the SA to conduct a complaint survey on an accredited hospital. In order for the SA to conduct a complaint survey against an accredited hospital, the RO must complete the Form CMS-2802 in ACTS approving the survey. Complaints that do not involve the potential of immediate jeopardy to patient health and safety should be investigated within 45 calendar days.

# 5130 - Conducting an Accredited Hospital Complaint Validation Survey

**(Rev. 1, 05-21-04)**

**SOM 3264**

The SA conducts the complaint validation survey of an accredited hospital based on a substantial allegation of noncompliance. A substantial allegation of noncompliance may be a complaint from a variety of sources. The complaint need not be formal, be directed toward CMS or the SA, or be a result of first-hand experience. The SA assigns surveyors who normally conduct surveys of non-accredited hospitals. The SA may request assistance from the RO if it is unable to conduct the investigation within a reasonable timeframe because of a shortage of specialist surveyors. If the complaint alleges a violation of the provisions of 42 CFR 489.24, or the related provisions of 42 CFR 489.20, follow the procedures found in §§5300-5370 of this manual. If a hospital refuses to permit a complaint survey, the SA follows the procedures in §3248.

Although an allegation may not warrant investigation, the RO sends a copy of the allegation to the accreditation organization if the allegation pertained to any survey or enforcement issues.

In most States, an engineer or other fire safety specialist surveys for compliance with the Life Safety Code (LSC) standard, and others survey the remaining standards in the Physical Environment Condition. If the hospital does not comply with the LSC standard, it becomes under SA jurisdiction, therefore; it is not necessary to survey the other standards associated with the physical environment condition. If a full survey is necessary, survey the remainder of the Physical Environment Condition, along with the other Conditions.

COMPLAINT SURVEYS ARE ALWAYS UNANNOUNCED. The SA does not disclose the identity of complainants, and does not involve them in the investigation unless specifically directed by the RO. The SA conducts the complaint survey in accordance with the survey protocol for hospitals. The SA uses the appropriate survey forms noted on the List of Documents in Certification Packet (See Exhibit 63) and the interpretative guidelines when performing the survey. The SA only surveys the Conditions related to the complaint, which are specified on the Form CMS-2802.

If the SA is unable to substantiate the complaint, it concludes the investigation promptly without an exit interview, but informs the Administrator of its findings. The SA completes Form CMS-2567 with the statement “No deficiencies found.” If the SA substantiates the complaint and/or finds Condition-level deficiencies during the course of the complaint investigation, it conducts an exit conference.

The SA conducts an exit conference with the provider/supplier at the completion of the complaint investigation survey when deficiencies are identified. The SA informs the

hospital of the survey findings including deficiencies found. The SA informs the hospital that survey findings will be documented on Form CMS-2567 which will be made available to the public under the disclosure of survey information provisions. The SA informs the hospital that the RO will inform the hospital of the disposition of the survey investigation.

If the deficiencies pose an immediate jeopardy, the SA prepares Form CMS-2567 and notifies the RO for immediate action. The SA forwards Form CMS-2567 to the RO within two working days following the finding of an immediate jeopardy situation. The SA completes Form CMS-670 at the conclusion of any survey conducted.

Substantiated with deficiencies and unsubstantiated with unrelated deficiencies are complaint records in which Federal deficiency(ies) are cited by the surveyor as a result of the investigation. Substantiated with no deficiencies and unsubstantiated with no deficiencies are complaint records in which Federal deficiencies are not cited by the surveyor as a result of the investigation. Substantiated with deficiencies means one or more of the allegations reported are verified and deficiencies were cited that are related to the allegations being investigated. Substantiated with no deficiencies means that one or more of the allegations reported occurred and is verified, but the allegations were corrected prior to the complaint investigation. Therefore, no deficiencies are cited. Unsubstantiated with unrelated deficiencies means that none of the allegations reported was verified, but deficiencies were observed and cited in other areas that are not related to the original allegations being investigated. Unsubstantiated with no deficiencies means that none of the allegations were verified and no deficiencies are cited.

## 5140 - Forwarding Investigation Report to RO

**(Rev. 1, 05-21-04)**

**SOM 3266**

The SA forwards survey documents as specified in Exhibit 63 to the RO at the conclusion of the survey investigation and enters survey data into the ACTS database in a timely manner.

If no Condition level deficiency is cited, SA will forward survey documents to the RO within 30 calendar days after the completion of the survey. If the RO determines that the accredited hospital is in compliance with the COPs investigated after review of the survey packet; the RO notifies the hospital and forwards a copy of the letter to the SA and the accrediting organization.

If a Condition level deficiency is cited and determined that it poses an immediate jeopardy to patient's health and safety, SA forwards the survey packet to the RO within 2 working days after the completion of the survey. If the RO determines after review of the survey packet that there are deficiencies that pose an immediate jeopardy (IJ) to patient health and safety, the hospital is placed on the 23-day termination track. The RO will

notify the hospital of the proposed termination action and request acceptable plans of correction. When acceptable plans of correction are received, the RO will direct the SA to conduct a revisit before the set termination date. The revisit will include a full survey of all COPs.

If a Condition level deficiency is cited but does not pose an Immediate Jeopardy to patient's health and safety, SA forwards the survey packet to the RO within 10 working days after the completion of the survey. If the RO determines after review of the survey packet that there are Condition level deficiencies that do not pose an immediate jeopardy (IJ) to patient health and safety, the RO will notify the hospital of the removal of its deemed status and places the hospital under SA survey jurisdiction. The RO will request the SA to conduct a full survey of all COPs at their earliest convenience.

If the hospital chooses not to submit a POC when no condition level deficiencies are found but deficiencies are found below the Condition level, the SA informs the hospital that survey findings will be documented on Form CMS-2567, which will be made available to the public under the disclosure of survey information provisions, and that the RO will inform the hospital of the disposition of the survey investigation.

## 5150 - Accredited Hospital Found in Compliance Following Complaint Validation Survey

**(Rev. 1, 05-21-04)**

**SOM 3268**

If no Condition level deficiency is cited at the conclusion of the survey investigation the hospital is determined to be substantially in compliance. This determination is still applicable if a Standard level deficiency cited. The SA forwards the survey packet to the RO within 30 calendar days after the completion of the survey. If after review of the survey packet the RO determines the accredited hospital is in compliance with the COPs investigated, the RO notifies the hospital and forwards a copy of the letter to the SA and the accrediting organization. No follow-up survey is conducted on Standard level deficiency citations. The hospital is not required to submit plans of correction for Standard level deficiency citations. If the hospital chooses not to submit plans of correction on Standard level deficiency citations, the SA reports any known information about the hospital's effort to correct the deficiencies. (see Exhibit 194)

## 5160 - Accredited Hospital Found Not in Compliance Following Complaint Validation Survey

**(Rev. 1, 05-21-04)**

**SOM 3270**

## 5160A - Not in Compliance - Immediate Jeopardy

**(Rev. 1, 05-21-04)**

If there are deficiencies that pose an immediate jeopardy to patient health and safety, the provider or supplier may be subject to termination by the RO. (See §§3010 and 5180.) The RO officially notifies the hospital (Exhibit 195) and forwards a copy of the letter to the SA and the accreditation organization.

When the SA finds one or more Condition level deficiencies that pose an immediate jeopardy to patient's health and safety the SA forwards the survey packet to the RO within 2 working days after the completion of the survey. If after review of the survey packet the RO determines that there are deficiencies that pose an immediate jeopardy (IJ) to patient health and safety, the hospital is placed on the 23-day termination track. See §3010. The RO will notify the hospital of the proposed termination action and request acceptable plans of correction. When acceptable plans of correction are received, the RO will direct the SA to conduct a revisit before the set termination date. The revisit will be a full survey of all COPs.

Acceptable plans of correction must contain the following elements:

- The plan of correcting the specific deficiency. The plan should address the processes that lead to the deficiency cited.

- The procedure for implementing the acceptable plan of correction for the specific deficiency cited.

- The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements.

- The title of the person responsible for correcting the deficiency and/or for implementing the acceptable plan of correction.

The termination action is rescinded if the IJ has been removed, and compliance is achieved and documented through the onsite verification. The SA will certify to the RO its findings and recommend that the termination action be rescinded. The RO will notify the hospital of its compliance status and that it is no longer under the SA survey jurisdiction. A copy of the letter is forwarded to the SA and the accrediting organization.

However, if the IJ has been removed but Condition level deficiencies still exist, the SA gives the hospital up to 67 additional calendar days or 90 calendar days total (23 plus 67) to achieve compliance. The SA will certify to the RO that the IJ has been removed and recommend that the 23-day termination action be rescinded and place the hospital on a non-IJ termination tract. The RO will notify the hospital of the new termination date and request that acceptable plans of correction are provided to the SA. The SA will schedule and conduct the revisit.

If complete compliance to the COPs is achieved by the hospital and verified during the second revisit, then the SA will certify its findings to the RO and recommend that termination action should be rescinded. The RO will notify the hospital of its compliance status and that it is no longer under the SA survey jurisdiction. A copy of the letter is forwarded to the SA and the accrediting organization.

However, in the event that the hospital failed to come into compliance, the SA will forward the complete survey packet to the RO within 10 calendar days. After review of the survey packet, the RO will send the hospital a final termination letter and publishes a public notice. The hospital will be terminated from the Medicare program.

## 5160B - Not In Compliance - Not Immediate Jeopardy

**(Rev. 1, 05-21-04)**

When the SA finds one or more Condition level deficiencies that do not pose an immediate jeopardy to patient's health and safety the SA forwards the survey packet to the RO within 10 working days after the completion of the survey. If the RO determines after review of the survey packet that there are Condition level deficiencies that do not pose an immediate jeopardy (IJ) to patient health and safety, the RO will notify the hospital of the removal of its deemed status and places it under SA survey jurisdiction. The RO will request the SA to conduct a full survey at their earliest convenience.

If the SA confirms that the hospital is in compliance with all the COPs during the full survey, the SA forwards the survey packet to the RO within 30 calendar days after the completion of the survey. No Condition level deficiency is cited, therefore, the hospital is substantially in compliance. If the RO determines that the accredited hospital is in compliance after review of the survey packet; the RO notifies the hospital and forwards a copy of the letter to the SA and the accrediting organization. No follow-up survey is conducted on Standard level deficiency citations. Deemed status of the hospital is restored.

If the SA confirms that one or more COPs are still out of compliance during the full survey, the SA will follow the 90-day termination procedure under §3012. No documents are forwarded to the RO. The SA will notify the hospital of the termination action and timelines. The SA will conduct the first revisit within 45 calendar days from the date of the survey.

If compliance to the COPs is achieved by the hospital during the first revisit, then the SA will certify its findings to the RO and recommend that termination action should be rescinded. The SA will forward the survey packet to the RO within 10 working days. The RO will notify the hospital of its compliance status and that it is no longer under the SA survey jurisdiction. Deemed status is restored. A copy of the letter is forwarded to the SA and the accrediting organization.

If the hospital remains out of compliance with one or more COPs during the revisit survey, the SA will certify its findings to the RO. The SA will notify the hospital of the continuation of the termination action and request acceptable plans of correction. When the SA had received acceptable plans of correction from the hospital, the SA will request from the RO an authorization to conduct a second revisit by the 60th day. Only the second revisit is subject to RO approval.

If complete compliance to the COPs is achieved by the hospital during the second revisit, then the SA will certify its findings to the RO and recommend that termination action should be rescinded. The SA will forward the complete survey packet to the RO within 10 working days. The RO will notify the hospital of its compliance status and that it is no longer under the SA survey jurisdiction. Deemed status restored. A copy of the letter is forwarded to the SA and the accrediting organization.

However, in the event that the hospital failed to come into compliance on the second revisit, the SA will forward the complete survey packet to the RO within 10 working days. After review of the survey packet, the RO will send the hospital a final termination letter and publishes a public notice. The hospital will be terminated from the Medicare program.

## 5170 - Reinstatement to Accreditation Organization Jurisdiction

**(Rev. 1, 05-21-04)**

**SOM 3272**

## 5170A - Hospital Under SA Monitoring

**(Rev. 1, 05-21-04)**

A hospital that has been under SA monitoring is returned to full accreditation status when the RO has determined that:

- The hospital’s major deficiencies have been corrected; and
- All the Conditions, including the LSC standard, are met.

## 5170B - Hospital Refused to Allow Survey

**(Rev. 1, 05-21-04)**

A hospital found out of compliance because of its refusal to allow a survey is returned to the accreditation organization's jurisdiction when:

- The hospital permits the validation survey to be conducted; and
- The hospital withdraws any prior refusal to authorize its accreditation organization to release a copy of its current accreditation survey.

## 5180 - Termination of Accredited Hospital

**(Rev. 1, 05-21-04)**

**SOM 3274**

Where deficiencies identified pose an immediate jeopardy, SA monitoring begins immediately, and the 23 calendar-day termination procedures described in §3010 apply.

Where there is noncompliance with a COP but the deficiencies are not an immediate jeopardy, the accredited hospital must be first placed under SA monitoring before further SA action can be taken. Thus, it may frequently take longer than 90 calendar days from the first documentation of noncompliance to the decision to terminate. Where the first full survey carried out under SA monitoring confirms that a Condition is still out of compliance, the RO applies the termination procedures described in §3012, and gives the hospital a reasonable time (up to 90 calendar days) in which to achieve compliance in accordance with an approved POC. As described in Step 3 of §3012, if the hospital alleges corrections have been or will be made timely, the SA conducts an appropriately timed revisit to determine whether compliance or acceptable progress has been achieved. If neither has occurred, the SA certifies noncompliance and forwards the certification and supporting documentation to the RO. See Step 4 of §3012.

## 5190 - Investigating Complaints Involving ESRD Services Provided by Accredited Hospitals

**(Rev. 1, 05-21-04)**

**SOM 3276**

Most of the hospitals participating in the ESRD program are accredited by JCAHO or AOA. "Deemed status" applies only to the hospital's approval as a provider, not to its status as a supplier of ESRD transplantation or dialysis services. The SA investigates all complaints and allegations related solely to ESRD services since ESRD services fall outside the purview of accreditation.

## 5200 - Investigation of Complaints Against Other Than Accredited/Deemed Providers and Suppliers

**(Rev. 1, 05-21-04)**

**SOM 3280-3298**

All the procedures in this section are mandatory when complaints involve Medicare, Medicaid, or CLIA facilities. The SA may, however, adopt more stringent guidelines. It is the SA's responsibility to ensure that the complaint data is entered into ACTS for any substantiated or unsubstantiated allegations that are investigated.

Investigation and resolution of complaints is a critical certification activity. The CMS, the SMA, and the SA are responsible for ensuring that participating facilities continually meet Medicare and Medicaid requirements. This requires prompt review by the SA and, if necessary, onsite investigation of reports alleging noncompliance and informing the RO and/or the SMA any time certification requirements are found to be out of compliance. The SA responsibility cannot be delegated.

## 5210 - SA Processing of General, Certification-Related Complaints

**(Rev. 1, 05-21-04)**

**SOM 3281**

The following procedures describe each step in the processing of a complaint, from receipt to closeout. As these activities are likely to cut across organizational lines, the SA establishes clear cut accountability for each aspect and a focal coordinating or controlling responsibility to assure timely and appropriate action. The SA enters information into ACTS for providers/suppliers that are required to use ACTS.

## 5210A - Collection

**(Rev. 1, 05-21-04)**

Complaints may come directly to the SA from individuals receiving services, or from their representatives. They may also be referred from the RO or other State, Federal, or private organizations. A complaint may be from a variety of sources, including complaints submitted in person, by telephone, through written correspondence, or in news media articles, that, if substantiated, would have an impact on the health and safety of patients, and that raises doubts as to a provider's or supplier's compliance with federal requirements. Allegations about Medicare, Medicaid, or CLIA facilities originate at a variety of State and local agencies. The SA must ensure that all of those organizations are aware of the SA's authority and responsibilities regarding complaints, and that they refer all allegations to the SA office.

The SA obtains the following information for every allegation:

- Complainant's name, address, and phone number, unless the complainant requests anonymity;
- Patient's or resident's Medicare number, if applicable;
- Facility's name and address; and
- Description of problem, including names, places, dates.

## 5210B - Control

**(Rev. 1, 05-21-04)**

Immediately after receipt, the SA establishes a file for the allegation. A control system should be used to facilitate tracking and control of the allegation until it is entered into ACTS.

## 5210C - Acknowledgment If Complainant Is Known

**(Rev. 1, 05-21-04)**

The SA promptly notifies the complainant in writing or with a telephone call that the complaint is being investigated, unless the RO or SMA that originally received the allegation has already done so. The SA does not delay acknowledgment pending an investigation unless the investigation will take place within three working days. The SA must take appropriate precautions to protect the complainant's anonymity and privacy. The SA maintains a copy of this notification with the complaint documentation.

## 5210D - Complaints - HHA Hotline

**(Rev. 1, 05-21-04)**

**(S&C 01-15; S&C 01-14)**

Each State has a Medicare home health hotline that can be called by patients who are dissatisfied with the home health services they are receiving or by other individuals with a complaint about a specific HHA. Under the Medicare COPs for Patient Rights at 42 CFR 484.10, HHAs are required to provide their patients with the hotline number for their state. Concerns about an HHA not complying with the COPs, or reports that an HHA is misinforming beneficiaries or inappropriately terminating care for patients, can be referred to the SA for investigation via the home health hotline. Concerned consumers may also call the SA directly. A violation of the COPs or the provider agreement could lead to termination of the HHA from the Medicare program.

As part of the patient rights COPs, the HHA is required to investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is, or fails to be, furnished, and to document both the existence of the complaint and resolution of the complaint.

Surveyors, as part of their investigation of the HHA's compliance of the COPs, may ask to review complaints received by the HHA and the resolution of these complaints. The HHA must permit examination of these records by or on behalf of CMS, or risk termination from the Medicare program.

## 5210E - Evaluation

**(Rev. 1, 05-21-04)**

### 1 - Referral

The SA evaluates any complaint to determine whether it should be retained in the SA for investigation or forwarded to the RO or other appropriate authority; e.g., for cases of billing complaints, the carrier, or the FI. Other State agencies or authorities may appropriately handle other concerns. Refer allegations involving the following to the RO within three working days:

- Accredited hospitals;
- Deemed HHAs;
- Federal facilities;
- Religious Nonmedical Health Care Institutions (RNHCIs)(evaluation performed by Region I, Boston, only);
- CLIA laboratories holding a certificate of accreditation. (See Chapter 6).
- CLIA-exempt laboratory. (See Chapter 6);
- Blood transfusion-related fatalities (See Chapter 6 and Appendix C);
- Over-utilization or inappropriate utilization of services within the QIO's jurisdiction;
- Civil rights violations; or
- Medicare or Medicaid fraud.

Refer all dumping complaints to the RO immediately. Refer all hospital and PRTF restraint/seclusion-related deaths to the RO immediately.

**2 - Notice**

Even if referral is not necessary, the SA considers whether any special notification is appropriate. If a complaint is especially significant and/or sensitive or is attracting broad public or media attention, the SA informs the RO immediately. Additionally, the SA needs to consider any other early notice requirements prescribed by other State or Federal polices or interagency agreements.

## 5210F - Investigation

**(Rev. 1, 05-21-04)**

**1 - Scheduling an Investigation**

If the allegation involves an immediate jeopardy to patient health and safety (See §3010), the SA investigates within two working days of receipt. Otherwise, follow the SA's existing procedures for prioritizing and investigating certification-related complaints (CMS is currently evaluating scheduling procedures for complaint investigations in non-accredited providers).

**2 - Conducting Investigation**

a - General Procedures

Complaint surveys are never announced. The SA assigns the investigation to an individual(s) with expertise in the specific areas involved in the allegation.

When conducting an onsite complaint survey, the SA explains the reason for the survey and avoids any impression that a predetermination has been made as to the validity of the allegation. The SA does not divulge the complainant's identity.

The SA uses the appropriate survey protocol and interpretive guidelines for the facility. The SA conducts a partial survey or an abbreviated survey for SNFs/NFs, focusing on the specific regulatory requirements related to the allegation. The SA reviews appropriate samples of residents, rooms, records, or services, as necessary, to assess compliance with applicable requirements (See Appendix P). If, based on an initial assessment or other observations, significant problems are identified, the SA expands the scope of review as necessary to determine compliance or noncompliance. Generally, it is not necessary to review records and information from more than one year ago. However, the SA is not precluded from doing so if concerns identified during the investigation indicate it is necessary in order to determine current compliance.

The complaint record becomes the basis for completion of Form CMS-2567.

Each allegation in the complaint record may be one of four types:

- Substantiated with deficiencies;
- Substantiated with no deficiencies;
- Unsubstantiated with unrelated deficiencies; or
- Unsubstantiated with no deficiencies.

Substantiated with deficiencies and unsubstantiated with unrelated deficiencies are complaint records in which Federal deficiency(ies) are cited by the surveyor as a result of the investigation. Substantiated with no deficiencies and unsubstantiated with no deficiencies are complaint records in which Federal deficiencies are not cited by the surveyor as a result of the investigation. Substantiated with deficiencies means one or more of the allegations reported are verified and deficiencies were cited that are related to the allegations being investigated. Substantiated with no deficiencies means that one or more of the allegations reported occurred and is verified, but the allegations were corrected prior to the complaint investigation. Therefore, no deficiencies are cited. Unsubstantiated with unrelated deficiencies means that none of the allegations reported was verified, but deficiencies were observed and cited in other areas that are not related to the original allegations being investigated. Unsubstantiated with no deficiencies means that none of the allegations were verified and no deficiencies are cited.

If a complaint record has deficiencies cited, the SA indicates all deficiencies on a Form CMS-2567 and obtains a POC, if appropriate. (See §2728.) The completed Form CMS-2567 must be made a part of the complaint record.

**b - Investigating Allegations of Substandard Patient Care**

When investigating allegations of substandard patient care, the SA evaluates not only the care furnished to individuals directly involved in the allegation, but also the institution's patterns of related care. The following is a suggested investigative approach oriented to health care. The SA should modify its approach, as appropriate, for other modes of treatment. Substandard patient care should not be confused with substandard quality of care for SNFs/NFs. (See Chapter 7 for substandard quality of care for SNFs and NFs).

**(1) Records and Record Maintenance**

The SA reviews a sample of individual records in relation to care plans and the consolidated patient records that are used by the nursing staff for evaluating care

needs. In performing this review, the SA looks for consistency of data on the physician's order sheet or progress notes, care plans, and cardex data.

The SA examines the facility's staffing charts for the time in question and may use payroll and patient records to confirm the actual presence of assigned staff on scheduled shifts.

If applicable, the SA reviews the sufficiency of physician supervision of patient care, including whether the attending physician countersigns written or oral orders. Frequently, oral orders identify situations in which physicians are not visiting the patients as frequently as required in the COPs or Requirements for Participation (RfP).

When a complaint investigation involves reviewing a SNF's or NF's pharmaceutical review practices, the SA should follow the procedures in Appendix N. If appropriate to the level of care, the SA reviews records maintained by the nursing staff to identify administration of medication and performance of treatment, verifying them against the physician order sheet, nursing care plan, and nursing notes data. The SA identifies and records practices used in identifying cancellation or addition of a particular drug or treatment.

**(2) Information from Nursing Personnel**

Depending on the nature of the complaint, the SA interviews nursing personnel about the availability of needed supplies and equipment, the procedures for scheduling patients for diagnostic procedures or treatment, and procedures for ordering and securing special diets.

**(3) Documenting Findings**

The SA records findings on the SRF and explain in the remarks section how the evaluation of the quality of care was made.

**(4) Assessment of Questionable Services**

The SA does not attempt to make a decision on the appropriateness of surgical or therapeutic-diagnostic services provided to a specific patient or group of patients.

If the SA receives an allegation that a facility is providing improper or inappropriate surgical, therapeutic, or diagnostic services, it refers the complaint to the RO. The RO will forward it to the QIO or appropriate regulatory agency for investigation.

## 5210G - Post-Survey Certification Actions

**(Rev. 1, 05-21-04)**

Following investigation, the SA records any findings on Form CMS-2567 and provides it to the facility per regular certification procedures. The SA requests a POC for any uncorrected deficiencies including a deficiency of the LSC requirement that is a part of the Physical Environment COP. See §2728.

Any subsequent certification actions depend on the nature of any deficiencies cited and the facility's willingness or ability to correct them.

When Federal deficiencies are identified, the SA initiates certification actions as follows:

1. **Immediate Jeopardy to Patient Health and Safety -** The SA certifies noncompliance and initiates expedited termination procedures. See §3010. See also §§7301 and 7307 for SNFs/NFs.

2. **COP/CoC/RfP Not Met (No Immediate Jeopardy) -** The SA certifies noncompliance and initiates procedures to recommend termination under §3012. See §3005 for Medicaid providers and §§7301 and 7310 for SNFs/NFs.

3. **Physical Environment Condition Not Met for Failure to Meet LSC (No Immediate Jeopardy in Nonaccredited Hospitals) -** The SA certifies noncompliance and initiate procedures as provided for nonaccredited hospitals. See §3012. See also §§7301, 7310, and 7410 for SNFs/NFs and §2480 for LSC waivers.

4. **All Conditions Met - Facility Unable or Unwilling to Provide Acceptable POC for Other Deficiencies -** A facility with deficiencies with respect to one or more of the standards in the COP or CfC may not participate without an acceptable POC 42 CFR 488.28(a). If it is unable to provide such a plan within a reasonable time (not more than 45 calendar days), the SA certifies noncompliance and forwards all related supporting documentation to the RO. See Chapter 7 for SNFs/NFs.

   A facility has a right to refuse to submit a POC if it believes it has enough evidence to show that a deficiency is invalid. The SA and/or the RO examines the documentation presented by a facility that a deficiency did not exist and reconsiders the deficiency determination. If necessary, the SA has the documentation reviewed by an individual who was not involved in making the original determination. If a deficiency did not exist, the SA removes the citation from the Form CMS-2567. If it is determined that the evidence indicates a deficiency, the SA explains the rationale to the facility and requests submission of a POC (See §7212 for nursing home requirements).

5. **All Conditions Met - Facility Provides Acceptable POC for Other Deficiencies -** The SA certifies compliance based upon an acceptable POC and assembles documentation for RO review.

6. **No Uncorrected Deficiencies** - No certification action is required.

## 5210H - Reporting

**(Rev. 1, 05-21-04)**

Since the RO or SMA is obligated to formally determine whether to continue or terminate participation based upon the SA certification, the SA should make all necessary certification documents available to them. For each complaint investigated, the SA completes Form CMS-562 (see Exhibit 75) and enters the record into ACTS. When deficiencies are cited, the SA completes Form CMS-562, Parts I and II, and Form CMS-2567, and forwards them to the RO or the SMA, as appropriate. When deficiencies are not cited, the SA completes Form CMS-562, Parts I and II, with the exception of Item #15. In this situation, Form CMS-562 is not forwarded to the RO or the SMA, but is entered into ACTS. Follow the SMA and SA procedure for title XIX facilities.

Specific SA post-investigation reporting requirements are as follows:

1. **SA Routine Reporting to RO or SMA (Complaints With Deficiencies) -** The SA reporting requirements which follow apply to complaint records with deficiencies cited that involve Medicare, Medicare/Medicaid, or Medicaid facilities.

   The SA reports complaints with deficiencies cited to the RO or SMA, as appropriate, using the following criteria:

   a. **Immediate Jeopardy to Patient Health and Safety.**

      (1) **Documentation to Be Completed** - Forms CMS-562, CMS-670, CMS-2567, and any appropriate supporting documentation.

      (2) **Reporting Deadline** - Three working days following the onsite visit.

   b. **COP/COC/RfP Not Met (No Immediate Jeopardy to Patient Health and Safety), or Facility Unable or Unwilling to Provide Acceptable POC for Other Deficiencies -**

      (1) **Documentation to Be Forwarded -** Forms CMS-562, CMS-670, CMS-2567, and any appropriate supporting documentation.

      (2) **Reporting Deadline** - 55 calendar days following onsite visit.

**c. All Conditions Met-Facility Provided Acceptable POC for Other Deficiencies**

**(1) Documentation to Be Forwarded** - Forms CMS-562, CMS-670, and CMS-2567.

**(2) Reporting Deadline** - 90 calendar days following onsite visit.

2. **SA Special Reporting to RO (Deficiencies Not Cited)** - The SA does not normally report to the RO when deficiencies are not cited during an investigation. However, the SA sends the completed Form CMS-562 and any documentation back to the RO when the complaint originated from the RO.

3. **Other Reporting (All Complaints)** - In addition to the RO reporting above, the SA closes out all complaints (substantiated and unsubstantiated) with a follow-up notice to the complainant informing him or her of the findings and disposition of the allegation. The SA sends this notice reasonably soon after the investigation and retains a copy with the complaint record.

4. The SA provides follow-up reports, as necessary, to any other appropriate parties such as the RO, the SMA, initial referring agencies, or ombudsmen, taking care to protect the privacy rights of the complainant.

## 5210I - Resolution/Closeout

**(Rev. 1, 05-21-04)**

### 1 - Deficiencies Not Cited

After any follow-up notices (see subsection G), the SA enters Forms CMS-562 and CMS-670 into ACTS and documents the facility's certification file. The SA does not send the package to the RO unless the complaint originated from the RO.

### 2 - Deficiencies Cited

The SA enters information from Forms CMS-562, CMS-670, and CMS-2567 into ACTS and files its copy of the certification documents in the facility's certification file. The SA sends the complaint package to the RO (Titles XVIII and XVIII/XIX) or SMA (Title XIX only), as appropriate.

Upon receipt of the SA report, the RO or SMA will process the action as it does any approval with a POC or adverse action. (See §§3010 and 3012, and §5500 for nursing homes). The RO or SMA will notify the SA of any additional needed actions, and will provide copies of any appropriate certification or notice documents.

## 5220 - RO Processing General, Certification-Related Complaints

**(Rev. 1, 05-21-04)**

**SOM 3284**

The extent and nature of RO involvement with a given complaint varies depending on the nature of the allegation and the receiving organization. The following procedures address the major variants of RO involvement.

## 5220A - Pre-Investigation Actions on Allegations Originating Through the RO

**(Rev. 1, 05-21-04)**

Most complaints originate through the SA and are recorded and controlled by the SA. When a complaint is filed directly with the RO, however, the RO assumes those initial SA responsibilities.

The RO establishes procedures and clear organizational accountability to ensure that any complaint originating through the RO is properly evaluated, documented, acknowledged, and handled timely and appropriately.

## 5220B - RO Processing of SA Investigated Complaints

**(Rev. 1, 05-21-04)**

The SA investigates most complaints, no matter where the allegation originated. Typically, the RO gets involved after an SA investigation if and when a certification action is needed, or in the situations set forth in §5210.E.

### 1 - SA Reporting

#### a - Complaints With Deficiencies Cited, Medicare, Medicare/Medicaid/CLIA Complaints

Following an investigation, the SA reports on each Medicare/Medicaid/CLIA certification-related complaint with deficiencies cited. It is the SA's responsibility to enter Parts I and II of Form CMS-562, Form CMS-670, and Form CMS-2567 into ACTS. The SA then sends the complaint package to the RO. The complaint package, at a minimum, must include Form CMS-562 (see Exhibit 75), Form CMS-670, and Form CMS-2567.

### b - Complaints With No Deficiencies Cited

The SA does not normally report to the RO on complaints with no deficiencies cited. It is the SA's responsibility to enter Items 1-14 of Form CMS-562 into ACTS. Part III of Form CMS-562 is not completed for complaints without deficiencies. The SA does not forward the complaint package to the RO unless the complaint originated with the RO. In this case, the SA completes Item 15. The RO completes Part III of Form CMS-562 when the complaint package is received.

## 2 - RO Actions

The RO acts on SA investigated complaints and certification documents as follows (See also Chapter 7 for SNF/NFs):

### a. Certification Actions (Complaints With Deficiencies Only)

The SA forwards certification documentation to the RO for any complaint with deficiencies cited. The RO processes as follows:

- **Immediate Jeopardy to Patient Health and Safety** - The RO processes under expedited termination procedures at §3010. The RO completes and enters Part III of Form CMS-562 into ACTS, following regular data entry and record-keeping procedures.

- **COP/COC/RfP Not Met (No Immediate Jeopardy)** - The RO processes as a termination under §3012 for all providers. The RO completes and enters Part III of Form CMS-562 into ACTS, following regular data entry and record-keeping procedures.

- **All Conditions Met - Facility Unable or Unwilling to Provide Acceptable POC for Other Deficiencies** - If the SA is not able to obtain an acceptable POC, it will send the RO the appropriate documents to process a termination. Terminate per procedures at §3012. The RO completes and enters Part III of Form CMS-562 into ACTS, following regular termination data entry and record-keeping procedures. The RO notifies the facility that only correction of the deficiencies will avoid termination.

- A facility has a right to refuse to submit a POC if it believes it has enough evidence to show that a deficiency is invalid. The RO examines the documentation presented by a facility that a deficiency did not exist and reconsiders the deficiency determination. If necessary, the RO has the documentation reviewed by an individual who was not involved in making the original determination. Disputes are usually resolved at the SA; however, in the event that the RO does a complaint survey or the SA is unable to resolve a problem, a facility may present the documentation to the RO. If a deficiency did not exist, the RO removes the citation from Form CMS-2567. If it is

determined that the evidence indicates a deficiency, the RO explains the rationale to the facility and requests the submission of a POC.

- **All Conditions Met - Facility Provides Acceptable POC for Other Deficiencies -** the RO reviews and approves, if appropriate, the POC. The RO completes and enters Part III of Form CMS-562 into ACTS, and files Form CMS-562 and Form CMS-2567 in the facility certification file.

**b. Complaint Records (Complaints With Deficiencies)**

In addition to processing the certification actions for any complaint with deficiencies cited, the RO completes Part III of Form CMS-562. The RO enters Part III of Form CMS-562 into ACTS and retains all hardcopy documents in the facility certification file.

**c. Special Processing**

In addition to the more routine reports, the RO may receive:

- **RO Referrals** - These consist of SA investigation reports, certification forms, etc. for allegations that originated with the RO and were subsequently referred to the SA for investigation.

In these instances, the RO closes out the established controls. If the complaint has:

  - **Deficiencies Cited** - Follow the same RO processing procedures the RO would use for SA complaints with deficiencies cited.

  - **No Deficiencies Cited** - Closeout the action and file documents in facility certification file. Complete and enter Part III of Form CMS-562 into ACTS.

- **Special Alerts -** In addition to SA reports following investigation, the SA may provide the RO with early alerts concerning complaints having special significance, sensitivity, or media involvement.

## 5220C - RO Processing of RO Investigated Complaints

**(Rev. 1, 05-21-04)**

This less frequent class of complaints includes allegations retained by the RO or forwarded to the RO by the SA for investigation or special processing. RO responsibilities vary based on the type of complaint.

**1 - Direct RO Investigation**

These procedures apply when direct RO investigation is called for, such as for Federal facilities, RNHCIs, or special situations where the RO opts to investigate directly. When directly investigating, the RO begins by ensuring that it or the SA has met all initial data collection and acknowledgment requirements in §5210.

If the allegation involves an immediate jeopardy to patient health and safety, the RO investigates within two working days. Otherwise, the RO schedules the investigation based on the severity of the allegation(s).

**2 - Conducting the Investigation**

The RO follows the procedures for investigation in §5200.

**3 - RO Documentation**

Following the investigation, the RO documents as follows:

a. **Allegations With No Deficiencies** - Completes Items 1-14 of Form CMS-562. Notifies the complainant and any other parties, enters the complaint record in ACTS, closes out any controls, and retains any complaint records in the facility's certification file. The RO does not perform steps 4 and 6.

b. **Allegations With Deficiencies** - Provides a statement of deficiencies to the facility and obtains a POC following routine certification procedures. Documents as follows:

- **For Immediate Jeopardy to Patient Health and Safety** - Completes Form CMS-562, Form CMS-2567, and any other appropriate supporting documents.

- **For COP/CfC/RFP Not Met (No Immediate Jeopardy to Patient Health and Safety), or Facility Unable or Unwilling to Provide Acceptable POC for Other Deficiencies** - Completes Form CMS-562, Form CMS-2567, and any appropriate supporting documents.

- **For All Conditions Met - Facility Provided Acceptable POC for Other Deficiencies** -Completes Form CMS-562 and Form CMS-2567.

- RO Completion Instructions For Form CMS-562

**Part I:** To be completed by the SA or RO. If the RO completes the form, except for Item 7B, it sends it with the complaint allegation to the SA. Item 7B is to be completed at the time Part II is completed by the investigating office.

**Part III**: Completed by RO (Titles XVIII and XVIII/XIX) or SMA (Title XIX only) if the complaint has deficiencies cited. If Part III is used, Items 16, 17, and 18 must be completed. Part III is completed for complaints with no deficiencies cited only if the complaint originated from the RO and was sent to the SA for investigation.

**4 - RO Action (Complaints With Deficiencies Only)**

The RO processes the preceding certification documents as follows:

a. **Immediate Jeopardy to Patient Health and Safety** - Processes under expedited termination procedures at §3010. Follows regular data entry and record-keeping procedures.

b. **COP/COC Not Met (No Immediate Jeopardy)** - Processes as a termination under §3012. Follows regular data entry and record-keeping procedures.

c. **All Conditions Met - Facility Unable or Unwilling to Provide Acceptable POC for Other Deficiencies** - If the SA was not able to obtain an acceptable POC, it will send the RO the appropriate documents to process a termination. The RO terminates per procedures at §3012, and follows regular termination data entry and record-keeping procedures.

d. **All Conditions Met - Facility Provides Acceptable POC for Other Deficiencies** -Reviews and approves, if appropriate, the POC. Files Form CMS-562 and Form CMS-2567 in facility certification file.

**5 - Notice**

Notify the complainant in writing concerning any findings.

**6 - Complaint Closeout (Complaints With Deficiencies Only)**

Ensure that Forms CMS-562 and CMS-2567 are entered into ACTS, closeout the action, forward a copy to the SA and the SMA, if appropriate, and retain all hardcopy documents in the facility certification file.

## 5220D - Special RO Processing

**(Rev. 1, 05-21-04)**

The following types of allegations are subject to special RO handling:

1. **Accredited Hospitals** - The RO follows procedures at §§5100-5190;

2. **CLIA Laboratories;**

3. **Blood Transfusion-Related Fatalities**;

4. **Over-Utilization or Inappropriate Utilization of Services** - The RO refers to the local QIO for investigation, records the allegation and findings on Form CMS-562, and documents facility files as for other allegations. The RO acts, as necessary, on any findings returned by the QIO;

5. **Civil Rights Violations** - The RO refers to the regional OCR for investigation. The RO records allegations and findings on Form CMS-562 and documents facility files as for other allegations. The RO acts as necessary on any findings returned by OCR; and

6. **Medicare/Medicaid/CLIA Fraud** - The RO refers to the RO of the Inspector General/DHHS for investigation. The RO records allegations and findings on Form CMS-562 and documents facility files as for other allegations.

In each of the above instances, the RO ensures that the complainant and SA are notified of any findings.

**Item 16 - Date of CMS RO/SMA Receipt**

Enter the date that Form CMS-562 is received in the RO (Titles XVIII and XVIII/XIX) or SMA (Title XIX only). The date must be greater than or equal to Item 15.

**Item 17 - CMS RO/SMA Action**

Enter the code of the final action by RO or SMA. Only one action may apply. Acceptable codes are 1 through 6.

**Item 18 - Date of Final Action Sign-off**

The date that the RO/SMA action was signed. The date must be greater than, or equal to, Item 16 (Date of RO/SMA Receipt).

## 5230 - RO Complaint Management

**(Rev. 1, 05-21-04)**

**SOM 3285**

General operating requirements for an RO program for processing general, certification-related complaints are discussed below.

## 5230A - Organizational Set-Up

**(Rev. 1, 05-21-04)**

The RO establishes clear accountability for coordination and control of complaints. The RO disseminates uniform procedures for recording allegations, referring them to the SA, ensuring adherence to procedures, and maintaining processing control systems.

## 5230B - Processing Control System

**(Rev. 1, 05-21-04)**

ACTS is a complaint processing control system. The RO uses ACTS to ensure timely and appropriated action on all allegations originating with or investigated by the RO. ACTS tracks allegations from their receipt through closeout.

## 5230C - Certification Procedures

**(Rev. 1, 05-21-04)**

If the facility file is being examined at the time of recertification, the RO reviews complaint documentation in the file. This historical data is a good indication of the facility's performance. The facility's POCs are good indicators of its responsiveness to correction requests.

## 5230D - Title XIX Oversight

**(Rev. 1, 05-21-04)**

The RO considers any complaint data regarding Medicaid-only facilities in targeting look- behind surveys or reviews.

## 5230E - Program Analysis

**(Rev. 1, 05-21-04)**

The RO will have specific data from all Forms CMS-562 in summary form - either through a log or data system. See §5060.

These records should include:

- Identification of region or State-wide patterns;
- Pinpointing of problem facilities or States;

- Evaluation of SA processing times, workloads, performance, etc.; and

- Identification of overall SA workloads, including unsubstantiated and Medicaid-only complaint volumes.

## 5230F - Training and Technical Assistance

**(Rev. 1, 05-21-04)**

The RO includes training and information needs identified above, as a basis for SA training, and technical assistance activities.

## 5240 - Hospital Restraints/Seclusion Death Reporting and Investigation

**(Rev. 1, 05-21-04)**

## 5240A - Background

**(Rev. 1, 05-21-04)**

The Centers for Medicare & Medicaid Services (CMS) hospital restraint and seclusion requirements are located in the Hospital COP, Patients' Rights; Interim Final Rule at 42 CFR 482.13, Standards (e) and (f). The SA will enter into ACTS information for patient deaths associated with restraint or seclusion.

The hospital restraint and seclusion death reporting requirement is located at 42 CFR 482.13(f)(7) and states "The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion."

Section 482.13(f)(2) states, "Seclusion or restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective."

The Interpretive Guidelines for 42 CFR 482.13(f)(2) state, "Emergency is defined as a situation where the patient's behavior is violent or aggressive and where the behavior presents an immediate and serious danger to the safety of the patient, other patients, staff, or others."

The Interpretive Guidelines for the Patients' Rights Standards (e) and (f), address the use of restraints in two situations: respectively, standard (e) use of restraints in medical and post-surgical care; and standard (f), emergency use of restraints in behavior management. For both situations, it is important to note that **these requirements are not specific to any treatment setting, but to the situation the restraint is being used to address**. Further, the decision to use a restraint is driven not by diagnosis, but by comprehensive individual assessment

that concludes that for this patient at this time, the use of less intrusive measures poses a greater risk than the risk of using a restraint or seclusion.

The intent of standard (f) "Seclusion and Restraint for behavior management" is to address the use of restraint or seclusion to manage violent behavior. A psychiatric diagnosis, behavioral health diagnosis, or a patient being treated in a behavioral health setting does not determine if restraint or seclusion use falls under standard (f); but rather, standard (f) addresses restraint or seclusion used to manage a patient's violent behavior. In situations when the patient was in seclusion or when the restraint was applied to address violent, aggressive, assaultive, etc. behavior toward self or others, the death reporting requirements of the behavior management standard apply. In these restraint or seclusion situations {behavior management} the death of **any patient that dies, for any reason**, while in restraint or seclusion **must** be reported to the CMS Regional Office (RO). Also **any patient's death** that occurs after seclusion or restraint {that had been applied/used for the management of violent behavior} has been discontinued **and** where the patient's death could be **reasonably related** to that patient having been in restraint or seclusion **must be** reported to the RO.

Unlike standard (f), standard (e) "Restraint for acute medical and surgical care" does not require death reporting. Therefore the hospital has no CMS death reporting requirement when the patient death occurs to a patient who was restrained for reasons other than behavior management. Behavior management includes managing behaviors that are violent, assaultive, or aggressive behavior directed towards oneself or toward others.

## 5240B - Hospital Reporting Methods

**(Rev. 1, 05-21-04)**

The hospital must report all patient deaths associated with the use of seclusion or restraint under 42 CFR 482.13(f)(7), in the following manner:

- By telephone, to their RO prior to the close of business the next business day after the patient's death, and

- By mail, to the Food and Drug Administration (FDA), using the "MedWatch FDA Form 3500A." The form must be properly and fully completed and forwarded within 10 working days of the patient's death.

The FDA will serve as a data collection source for the MedWatch 3500A reports and will forward these reports to CMS. Instructions for completing the MedWatch FDA 3500A can be found on the FDA MedWatch Web site.

The CMS requires the accredited or nonaccredited hospital to report patient restraint or seclusion deaths to the hospital's RO for the circumstances and in

the methods and times stated in the previous paragraphs. The hospital is **not** to postpone reporting the patient's death until after the hospital's investigation. The hospital is reporting to CMS that a patient died while in behavior management restraint or seclusion, or that the death could reasonably be related to the patient having been in seclusion or restraint; not the cause of the patient's death.

## 5240C - Responsibilities

**(Rev. 1, 05-21-04)**

Hospitals will report patient deaths associated with restraint or seclusion, as previously discussed, to their RO. Any hospital patient restraint or seclusion death report received by a State Agency (SA) directly from a hospital (or other source) will be immediately forwarded to its RO the day the SA receives the report.

The RO will maintain restraint/seclusion death report data. Each RO will designate one contact person and a backup person who will serve as the point of contact, coordination, and communication regarding reporting, investigation and follow-up for the death-reporting requirement under Patients' Rights.

The CMS Central Office (CO) contact will maintain the central death report roster and a copy of all death report worksheets collected. CO will contact ROs as needed during each investigation for updates until the investigation is complete.

SAs are to notify the hospitals in their State that hospitals must report to their RO any death that occurs while a patient is restrained or in seclusion (for management of behavior, standard (f)), or where it is reasonable to assume that a patient's death is a result of restraint or seclusion (used to manage violent behavior). State agencies are to provide hospitals with their RO contact name and telephone number, as well as the hospital reporting procedures contained in this policy.

## 5240D - Process

**(Rev. 1, 05-21-04)**

Based on telephone communications between the hospital and the RO, the RO will evaluate the information provided by the hospital to determine if the situation applies to seclusion or restraint use under 42 CFR 482.13(f)(7), or if the situation applies to restraint use under 42 CFR 482.13(e). If the restraint/seclusion death report applies to the behavior management standard, within 2 working days of receiving the report, the RO will immediately notify the SA to authorize a survey to investigate the hospital's compliance with the

Patient's Rights COP at 42 CFR 482.13 (including investigating the reported death). The RO will provide the SA with all the data that has been obtained for the Restraint/Seclusion Death Report Worksheet prior to the investigation. Worksheet information not provided to the RO during its telephone communication with the hospital will be obtained by the SA during the survey.

In addition to notifying the SA and authorizing the survey, within 2 working days of receiving the report, the RO will notify CO, the hospital's accrediting organization (AO), if accredited, and the appropriate state Protection and Advocacy Group (P&A). The RO will provide the following information to the hospital's AO and P&A: hospital's name, hospital's address, patient's name and date of death. THIS IS THE **ONLY** INFORMATION TO BE SUPPLIED TO THESE ORGANIZATIONS. The names and information about each State's P&A can be located at the following Web site: http://www.protectionandadvocacy.com.

In accordance with the State Operations Manual, the SA will handle each restraint/seclusion death report as a complaint investigation. The SA should complete investigations within five working days of receipt of survey authorization from the RO.

In addition to its regular complaint investigation paperwork, the SA will complete the Restraint/Seclusion Death Report Worksheet. The worksheet is for use by the SA and CMS to gather information and to track the investigation. The worksheet is not to be forwarded to the hospital for completion. The SA will gather the remaining information for completion of the Restraint/Seclusion Death Report Worksheet during its investigation. Within two working days of completion of the survey, the SA will email or fax a copy of the fully completed Restraint/Seclusion Death Report Worksheet to the RO. The SA is to ensure that all information requested within the worksheet is provided.

Within two working days following receipt of the worksheet from the SA, RO will e-mail (or Fax) a copy of the completed Restraint/Seclusion Death Report Worksheet to the CO contact. The CO will review the status of all outstanding restraint/seclusion death reports with each region regularly.

## 5250 - Complaints Involving HIV-Infected Individuals

**(Rev. 1, 05-21-04)**

**SOM 3298**

As direct recipients of Federal funds, providers and suppliers are subject to provisions of §504 of the Federal Rehabilitation Act of 1973. Symptomatic and asymptomatic individuals who are infected with the human immunodeficiency virus (HIV), or "AIDS virus," are protected by the Rehabilitation Act as "individuals with handicaps."

Therefore, HIV-infected individuals who are provided services, are employed, or are to be employed by providers and suppliers in Federally-conducted or financed programs or activities would be treated like anyone else in the workforce, so long as these individuals do not, on a case-by-case basis, pose a substantial health and safety risk to others, or pose a performance problem, and are "otherwise qualified."

A facility participating in the Medicare or Medicaid programs cannot discriminate against individuals who are HIV-infected so long as these individuals do not, on a case-by-case basis, pose a substantial health and safety risk to others and so long as the facility provides comparable services and care to non HIV-infected individuals.

The SA or the RO refers discrimination complaints to OCR, which is the authority to determine whether Medicare or Medicaid providers and suppliers comply with this non-discrimination statute.

## 5300 - Investigations Involving Alleged EMTALA Violations

**(Rev. 1, 05-21-04)**

**SOM 3400**

Section 1866 of the Act, Agreements with Providers of Services, specifies that for a hospital, or any provider of services, to qualify for participation in the Medicare program, it must enter into an agreement with the Secretary of HHS. Effective August 1, 1986, participating hospitals with emergency departments must comply with the requirements of §1867 of the Act as a condition of their provider agreement.

The following Medicare provider agreement requirements, which closely parallel provisions contained in §1866 of the Act, must be met by Medicare participating hospitals with emergency departments:

- 42 CFR 489.20(l) requires a hospital to comply with the requirements of 42 CFR 489.24. Section 1866(a)(1)(I) of the Act requires a hospital to have and enforce policies to ensure compliance with the requirements of §1867;

- 42 CFR 489.20(m) requires a hospital to report to CMS or the SA any time it believes it has received an individual who has been transferred from another hospital in violation of 42 CFR 489.24;

- 42 CFR 489.20(q) requires a hospital to post conspicuously a sign(s) specifying the rights of individuals, under §1867 of the Act, with respect to examination and treatment for emergency medical conditions and women in labor and to indicate whether or not the hospital participates in the Medicaid program;

- 42 CFR 489.20(r)(1) requires a hospital to maintain medical and other records related to individuals transferred, including discharges, to or from the hospital for a period of five years from the date of transfer;

- 42 CFR 489.20(r)(2) requires a hospital to maintain a list of physicians who are on call to provide treatment necessary to stabilize an individual with an emergency medical condition;

- 42 CFR 489.20(r)(3) requires a hospital to maintain a central log on each individual who comes seeking assistance and whether he or she refused treatment, was refused treatment, or whether the individual was transferred, admitted and treated, stabilized and transferred, or discharged.

When hospitals do not conform to the requirements of §1867 of the Act, the practice is commonly called "dumping." A hospital with an emergency department is defined in 42 CFR 489.24(b) as a hospital that offers services for emergency medical conditions within its capacity to do so. The regulations at 42 CFR 489.24 parallel the provisions of §1867 of the Act and contain the requirements that a hospital with an emergency department must meet.

If a hospital fails to meet these requirements, CMS may terminate the provider agreement in accordance with 42 CFR 489.53. The Office of the Inspector General (OIG) has the responsibility and authority to assess civil monetary penalties (CMPs) or to exclude physicians from the Medicare program when a hospital or physician violates these requirements. Additionally, individuals suffering personal harm and medical facilities suffering financial loss as a result of a violation of these provisions can bring civil action under State law against the offending hospital and physicians. Filing for such civil action is limited to a period of two years after the date of the alleged violation. This legislation does not preempt any State or local laws, except to the extent that State or local requirements directly conflict with a requirement of this legislation.

## 5310 - Basis for Investigation

**SOM 3402**

The SA will enter EMTALA violations into ACTS. The RO will approve or disapprove EMTALA investigations in ACTS.

## 5320 - RO Direction of Investigation

**(Rev. 1, 05-21-04)**

**SOM 3404**

## 5320A - Evaluation of Allegation

**(Rev. 1, 05-21-04)**

The RO evaluates all complaints and refers to the SA those that warrant SA investigation. The SA or the RO also sends a letter to the complainant acknowledging the complaint and informing the complainant of whether an investigation is warranted. The SA's responsibility is to ascertain, via investigation, whether a violation of 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20 occurred, and if there were other violations.

## 5320B - Request for Investigation of Allegations

**(Rev. 1, 05-21-04)**

The RO gives an initial verbal authorization for investigation, then prepares a Form CMS-1541A, Request for Survey of 42 CFR §§489.20 and 489.24, Essentials of Provider Agreements: Responsibilities of Medicare Participating Hospitals in Emergency Cases) (Exhibit 136) and forwards to the SA a copy of the allegation(s). The RO also sends the SA Form CMS-562, Medicare/Medicaid/CLIA Complaint Form, along with the Form CMS-1541A. If the RO identifies conditions or standards it wants the SA to survey, related to the dumping allegation at an accredited hospital, the RO completes the Request for Validation of Accreditation Survey, Form CMS-2802 and sends it to the SA in accordance with §5120. If the RO identifies conditions or standards it wants the SA to survey relating to the dumping allegation at a non-accredited hospital, it will inform the SA via a memorandum sent along with the Form CMS-1541A.

## 5330 - Conducting an Investigation

**(Rev. 1, 05-21-04)**

**SOM 3406**

## 5330A - Selecting the Team

**(Rev. 1, 05-21-04)**

To perform the investigation, select surveyors with a background in the profession or area to be investigated. Preferably, personnel should have acute care training and experience;

all surveyors must be adequately trained in the evaluation of 42 CFR 489.24 cases. Physicians should have experience in peer review.

Appropriate physician review may be performed by qualified SA physicians or under agreements or contracts with the State QIO, the State or local medical associations, or other physician groups or individuals. If a SA physician is not available and a medical review appears to be needed, indicate on the "Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report," Form CMS-1541B, (Exhibit 137), that a physician review is recommended, and send all of the information to the CMS RO. The RO will authorize the appropriate QIO or physician consultant to perform the review, if needed. If the QIO is requested to provide a medical advisory review of the medical record(s) it must be completed within five (5) working days. Physician reviewers should be board certified, although it is not required, and they should be actively practicing in the same specialty, or specialties, as the physician or physicians who treated the patient whose case resulted in the complaint.

## 5330B - Scheduling the Investigation

**(Rev. 1, 05-21-04)**

Allegations of dumping made against a hospital, non-accredited or accredited, represent a probable immediate jeopardy to the next individual who comes to the hospital requesting examination and treatment for an emergency medical condition. Therefore, complete the investigation within five working days after receipt of the telephone authorization from the RO. DO NOT ANNOUNCE ANY INVESTIGATIONS.

## 5330C - Guidelines for Surveyors Conducting Investigations

**(Rev. 1, 05-21-04)**

1 - Attention to Procedures

The purpose of conducting the investigation is to ascertain whether or not the hospital violated 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20. The inspection must be in accordance with applicable survey procedures and policies. Review instructions in Appendix V, "Interpretive Guidelines and Survey Procedures," before beginning the investigation.

2 - Involvement of Complainants

Complainants, if known, will receive a letter of acknowledgment from the SA or RO. Do not disclose the identity of complainants. When information obtained during the investigation appears to be in conflict with the information supplied by the complainant, consult with the complainant, if this can be done without disclosing the person's identity.

## 5330D - Conducting the Investigation

**(Rev. 1, 05-21-04)**

To investigate allegations of noncompliance with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20, use interpretive guidelines and survey procedures in Appendix V. The guidelines provide a detailed interpretation of the regulations.

A complete investigation consists of assessment of the following components:

- Completeness, adequacy, and enforcement of policies and procedures which address the provisions of 42 CFR 489.24;
- Prompt reports to the SA or CMS of receipt of an improperly transferred individual by the receiving hospital;
- Presence and completeness of signs posted in emergency departments specifying the rights of individuals under 42 CFR 489.24, and information indicating whether the hospital participates in the Medicaid program;
- Maintenance of medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of transfer, including discharged patients;
- Maintenance of a list of physicians who are on call to provide necessary stabilizing treatment;
- Maintenance of a central log on each individual who comes to the hospital seeking emergency services;
- Provision of an appropriate medical screening examination sufficient to determine the presence of an emergency medical condition;
- Provision of necessary stabilizing treatment;
- Provision of no delay in examination or treatment in order to inquire about insurance status or capability for payment;
- Provision of an appropriate transfer to another medical facility;
- Provision of whistleblower protections; and
- Adequacy of responsibilities of the recipient hospital with specialized capabilities (nondiscrimination).

The survey tasks are listed below for easy reference. See Appendix V for detailed guidance.

- Task 1: Entrance Conference
- Task 2: Case Selection Methodology
- Task 3: Record Review
- Task 4: Interviews
- Task 5: Exit Conference
- Task 6: Professional Medical Review
- Task 7: Assessment of Compliance and Completion of the Deficiency Report

After the investigation is concluded, complete a Form CMS-1541B, "Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report," (Exhibit 137). If one or more of the provisions at 42 CFR 489.24 or the related requirements of 42 CFR 489.20 are not met, complete a "Statement of Deficiencies and a POC," Form CMS-2567, using the "Principles of Documentation." Describe in detail the facts of each individual case. In addition, specify whether the hospital was aware of the problem and took steps to remedy it prior to the survey. If a SA physician was a member of the investigation team, include the medical review of the case. Use the "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals," (Exhibit 138) for this purpose. In addition, complete the Form CMS-562. All forms must be signed, showing the professional titles of all participating surveyors, and dated.

## 5330E - Exit Conference

**(Rev. 1, 05-21-04)**

It is usually desirable and appropriate to conduct an exit conference. You may outline the basic facts uncovered by the onsite investigation. However, you must inform the hospital that the RO will make the final compliance determination, and the determination is often made with information obtained after the onsite investigation. Do not reveal the complainant and do not venture an opinion on what determination the RO might make. The exit conference should include a description of the process that is followed if the RO determines that a violation has occurred.

## 5340 - Forwarding Report of Investigation to the RO

**(Rev. 1, 05-21-04)**

**SOM 3408**

Forward the results of the investigation and your recommendations to the RO by the fastest method available within ten working days following completion of the onsite survey, if it appears there may be a violation of §§1866 or 1867 of the Act. If there appears to be no violation, and the COPs have been met, this timeframe may be extended to 15 working days, in order to allow the RO additional processing time. Send the following materials to the RO in one package:

- Form CMS-562,"Medicare/Medicaid/CLIA Complaint Form";

- Form CMS-1541B, "Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report." Recommend one or more of the actions below on the form:

    1. **None** - This means the complaint was not substantiated;

    2. **In Compliance, but Previously Out of Compliance** - This means that the hospital identified the problem on its own and took effective corrective action prior to the investigation. In addition to this recommendation, document on the Form CMS-2567 when the hospital identified the violation or a similar problem, the corrective action taken, and the date of such action. Also, document that the hospital has had no violations or similar problems for at least the past 6 months;

    3. **Recommend Termination (23 calendar day track) -** This means that the hospital is out of compliance with 42 CFR 489.24 or the related requirements at 42 CFR 489.20(l), (m), (q) or (r) and the violation presents an immediate jeopardy to patient health and safety;

    4. **Recommend Termination (90 calendar day track) -** This means that the hospital is out of compliance with 42 CFR 489.24 or the related requirements at 42 CFR 489.20(l), (m), (q) or (r), but the violation does not present an immediate jeopardy to patient health and safety;

    5. **Request Physician Review -** This means that it is recommended that the RO obtain a medical review of the case;

    6. **Possible Discrimination -** This means that it is believed that discrimination occurred based on financial status, race, color, nationality, handicap, or diagnosis.

- Form CMS-670, “Survey Team Composition and Workload Report”;

- Form CMS-2567, “Statement of Deficiencies and POC.”

If the hospital identified the deficiency and took corrective action prior to the investigation, indicate on the Form CMS-2567 that the requirement was not met. However, indicate on the Form CMS-2567 and the narrative report that the hospital took corrective action prior to the investigation, what action was taken, and for how long the hospital has been in compliance.

- Physician Review Outline for Emergency Care Obligations of Medicare Hospital (if physician review was done by SA);

- Complaint investigation narrative;

- Copies of pertinent hospital policies and procedures that relate to the identified deficiencies;

- Certification of benefits versus risks of the transfer, if this is a transfer case;

- Summary listing of all patients comprising the sample, including an explanation of how and why the cases were selected for review;

- Summary of interviews; and

- Copies of medical records for substantiated cases, medical records of individuals named in complaints, and any medical records for which a QIO review is requested.

## 5350 - RO Review of Investigation

**(Rev. 1, 05-21-04)**

**SOM 3410**

Upon receiving the case from the SA, the RO has 10 working days to review the investigation findings. The RO is encouraged to confer with the SA, and may also request medical review of the case by the appropriate QIO or State Agency physician reviewer to determine if there is a dumping violation. If medical review is required, the RO has five working days to review the case upon return from the QIO. With this information, and any other additional information, the RO determines whether the hospital complied with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20, and determines whether the violation constitutes an immediate jeopardy to patient health and safety.

Prior to determining compliance or noncompliance, the RO is encouraged to confer with the State Agency, and **may** confer with the hospital's representatives and share data as possible as limited by current Privacy Act requirements.

## 5350A - Hospital Is In Compliance - No Past Violation

**(Rev. 1, 05-21-04)**

If the RO determines that the allegation is not substantiated and that the hospital is in compliance with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20, the RO notifies the hospital and forwards a copy of the letter to the SA. If the SA received the complaint, it will notify the complainant that the complaint was not substantiated. If the RO received the complaint, the RO will notify the complainant.

## 5350B - Hospital Is In Compliance - Past Violation, No Termination

**(Rev. 1, 05-21-04)**

If the RO determines that the allegation was substantiated, but the hospital identified the violation on its own, took effective corrective action prior to the investigation, and has had no violations of 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20 for at least the past 6 months, termination action is not initiated. The RO notifies the hospital via a "Past Violation - No Termination Letter" and forwards a copy of the letter to you. The RO or SA also sends a copy of the letter to the hospital and to the complainant. Although no termination action is taken, the RO must refer past violations of 42 CFR 489.24 to the OIG for assessment of civil monetary penalties (CMPs).

## 5350C - Hospital Is Not in Compliance - Immediate Jeopardy to Patient Health and Safety

**(Rev. 1, 05-21-04)**

If the RO determines that the hospital is not in compliance and the violation represents an immediate jeopardy to patient health and safety, the RO follows a 23 calendar-day termination process. Uncorrected deficiencies that resulted in a violation of 42 CFR 489.24 may pose an immediate jeopardy to people seeking emergency care. The termination procedures in §3412.A are followed. The RO will notify the complainant that the complaint was substantiated. It will also inform the hospital in writing of the specific violations via a preliminary determination letter, and will send the hospital a copy of "Statement of Deficiencies," Form CMS-2567. The SA will also receive a copy of the letter.

## 5350D - Hospital Is Not in Compliance - Situation Does Not Pose an Immediate Jeopardy to Patient Health and Safety

**(Rev. 1, 05-21-04)**

If the RO determines that the hospital is not in compliance with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20, but the violation does not pose an immediate jeopardy, or the hospital took corrective action after the investigation to remove the immediate jeopardy, the RO follows a 90 calendar-day termination process. The termination procedures in §3412.B are followed. The RO notifies the complainant that the complaint was substantiated. The RO also informs the hospital, in writing, of the specific violations via a preliminary determination letter and sends the hospital a copy of Form CMS-2567, "Statement of Deficiencies." The SA will also receive a copy of the letter.

Examples of noncompliance that usually do not pose an immediate jeopardy include the following scenarios:

1. A transfer which was appropriate, but not signed or dated by the physicians;

2. An appropriate, functioning, central log that on one particular day is not fully completed; and

3. A written hospital policy that is missing, but is nonetheless being implemented.

The fact that the hospital has completed a POC should not be interpreted to mean that the hospital admits violating §§1866 or 1867 of the Act. However, the hospital will still be included on the log of facilities with §§1866 and 1867 violations, with the notation that an acceptable POC was received by CMS, and termination action was stopped.

## 5355 - RO Procedures for Coordinating Statutorily Mandated QIO (5-day) Review of Alleged Violations of 42 CFR 489.24

**(Rev. 1, 05-21-04)**

Prior to terminating a hospital from the Medicare program because of possible violation(s) of EMTALA, the RO shall request the appropriate QIO to assess whether the individual involved was provided an appropriate medical screening examination, stabilizing treatment, or an appropriate transfer as required by 42 CFR 489.24.

The QIO 5-day review is required if the RO determines that a case involves a possible violation of 42 CFR 489.24 to support possible termination action against a hospital if in fact it violated EMTALA. The RO shall have the QIO assess whether an appropriate medical screening examination, stabilizing treatment, or an appropriate transfer was required. The QIO shall complete the review within 5 working days and provide a copy of the report to the RO. It is not required that the physician reviewer give the hospital

and/ or physician an opportunity to respond to the allegations at this time. If the affected physician and/or hospitals have questions concerning the case, they are to consult with the RO.

The QIO review is not required in cases where a delay in effecting a sanction would jeopardize the health and safety of individuals or in situations where medical review is inappropriate (e.g., cases where the individual was denied a medical screening examination). The QIO 5-day review is required to seek medical expertise on whether the individual was adequately screened, examined and treated.

The RO is responsible for providing the QIO with all information relevant to the case that is within its possession and control. The RO sends the "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals," (Exhibit 138) to capture this information.

The RO shall release the QIO review to the affected physician and/or hospital, when the RO has made a determination as to whether the hospital violated or is in compliance with EMTALA. In addition, the RO may release the QIO review to the individual or his or her representative upon their request according to the Freedom of Information Act (FOIA). The physician reviewer's identity is confidential therefore when releasing the QIO report the physician's identity is not to be disclosed unless he or she consents to the release of their identity in accordance with the disclosure regulations at 42 CFR 480.132 and 480.133.

These cases in which the RO determines the hospital to be in compliance with 42 CFR 489.24 or to be in violation of 42 CFR 489.20 of the EMTALA regulation do not need to be forwarded to the QIO for review. The RO shall take the appropriate actions as indicated.

## 5360 -Termination Procedures for Violations of 42 CFR 489.24 and/or the Related Requirements at 42 CFR 489.20(l), (m), (q), and (r)

**(Rev. 1, 05-21-04)**

**SOM 3412**

## 5360A - Procedures for Termination When the Violation of 42 CFR 489.24 Is an Immediate Jeopardy to Patient Health and Safety

**(Rev. 1, 05-21-04)**

If the RO determines that an immediate jeopardy exists, the termination procedures are completed within 23 calendar days. The processing time frames are the maximum allowed. The procedures are not postponed or stopped unless evidence of correction of the deficiencies or proof that the violation did not exist is obtained. The case is referred to the OIG that has responsibility for assessment of the CMPs against the hospital and/or

physician and physician exclusion provisions for violations of 42 CFR 489.24. In addition, the RO simultaneously forwards supporting documents to the appropriate QIO (for 60 day QIO review) to provide a medical opinion on the case and to the OIG. The case is also referred to the Office for Civil Rights (OCR) because OCR may take action under the Hill-Burton Subpart G Community Services regulations at 42 CFR 124.603(b)(1).

The 23-day termination procedure is as follows:

1. **Day One -** This is the date on which the RO makes the determination of noncompliance with 42 CFR 489.24. It is the date of the preliminary determination letter. To letter will be forwarded to the hospital by the fastest method available (fax, e-mail or telephone). In addition, a written letter will followed up by mail. The preliminary determination letter informs the hospital:

    - Of the RO's findings based on the investigation and the results of medical review, (if sought by the RO);

    - Of the projected termination date (the 23rd calendar day from the date of the preliminary determination letter);

    - Of the date on which the RO will issue a Notice of Termination Letter and notify the public (at least two calendar days, but no more than four calendar days prior to the termination date); and

    - That the hospital may avoid the termination action and notice to the public by either providing credible evidence of correction of the deficiencies or by successfully showing that the deficiencies did not exist.

In either case, the necessary information must be furnished to the CMS RO in time to have an opportunity to verify the corrections before the projected termination date.

2. **Nineteenth Calendar Day -** The RO sends a Notice of Termination letter to the hospital and the State Medicaid agency if the hospital also participates in the Medicaid program. A public notice of the termination action is prepared.

3. **Twenty-First Calendar Day** - The public notice is published.

**NOTE -** The RO notifies the public of the proposed termination action by the most expeditious means available. A newspaper notice or a press release to the radio and television stations serving the area is all appropriate options. The notice must be made at least two calendar days, but no more than four calendar days prior to the effective date of termination.

4. **Twenty-Third Calendar Day** - Termination takes effect unless compliance has been achieved or threat has been removed.

The hospital has an opportunity to develop and implement a plan of corrective action. If the hospital alleges compliance or provides credible evidence that the immediate jeopardy to patient health and safety has been removed after initiation of termination action, the RO will direct a resurvey. If that evidence is verified, the RO will switch from the 23 calendar-day termination procedures to the 90 calendar-day procedures (the termination date does not start a new cycle. The count continues from the date the switch to 90-day track occurs). This allows the hospital time to prove that the corrective action is good for the long-term (i.e., the corrective action is adequate to ensure that no further violations will occur). The RO will direct the SA to conduct a second survey within 60 calendar days of the first. On the resurvey, examine emergency records for the period since the last survey to assess continued compliance. The RO will send the complainant a letter reporting the final results of the investigation.

If the termination takes place and the hospital desires to become re-certified as a Medicare provider, the hospital must provide reasonable assurance that compliance will be maintained. This means that sustained compliance must be demonstrated over a period of time, as determined by the CMS RO. The hospital must have no cases of "dumping" for up to 30 calendar days prior to the onsite survey in order to regain Medicare certification. Determine this through a rigorous review of emergency service records, as well as staff interviews during the onsite survey. When continued monitoring is appropriate to assure that corrective action has been taken, the RO will inform the provider of the period for which such monitoring will continue.

## 5360B - Procedures for Termination When the Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20 Is Not Considered an Immediate Jeopardy to Patient Health and Safety

**(Rev. 1, 05-21-04)**

1. **Day One** - This is the date on which the RO makes the determination of noncompliance with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20. It is the date of the preliminary determination letter.

2. **Calendar Day 70** - The RO sends a Notice of Termination letter to the hospital and a copy to the State Medicaid agency if the hospital also participates in the Medicaid program. The public notice of the termination action is prepared.

3. **Calendar Day 75** - The public notice is published.

   **NOTE -** The RO notifies the public of the proposed termination action by the most expeditious means available. A newspaper notice or press releases to the radio and television stations serving the area are all appropriate options. The notice must be made fifteen calendar days prior to the effective date of termination.

4. **Calendar Day 90 -** Termination takes effect unless compliance has been achieved or threat has been removed.

## 5370 - RO Procedures for Coordinating Statutorily Mandated QIO Review of Confirmed Dumping Cases

**(Rev. 1, 05-21-04)**

**SOM 3413**

Before imposing sanctions under §1867 of the Act for violations of 42 CFR 489.24, 42 CFR 489.24(h) requires that CMS obtain consultation from the appropriate QIO. The OIG holds the authority to assess CMPs against the hospital or physicians or to exclude physicians from the Medicare program for violations of 42 CFR 489.24.

## 5370A - Procedures for Coordinating Calendar 60 day QIO Review

**(Rev. 1, 05-21-04)**

When the RO determines that a hospital was non-compliant with the requirements of 42 CFR 489.24, one of its notice requirements is to notify the OIG that the violation was confirmed and that termination action has been initiated. (See Exhibit 208.) With the notification letter, the RO attaches a copy of the following documents:

- Form CMS-1541B;
- Form CMS-2567;
- Medical record;
- Summary of interviews;
- Explanation of sample selection;
- Copies of pertinent hospital policies and procedures related to the identified deficiencies;
- Complaint investigation narrative;
- Certification of benefits versus risks of the transfer (if this is a transfer case); and
- Copy of the 5 working-day advisory MR (if the RO had requested such a review to make its compliance determination).

The RO sends the above information, and any other pertinent documentation in its possession to the OIG at the following address:

U. S. Department of Health and Human Services
Office of Inspector General
Office for Civil Fraud and Administrative Adjudication
Cohen Building, Room 5600
330 Independence Avenue, S. W.
Washington, D. C. 20201

At the time of referral to the OIG, the RO asks the appropriate QIO (with a contract under Part B of title XI of the Act) to provide a medical opinion on the case and to forward the report to the OIG within 60 days. The RO uses the "Model Letter Requesting QIO Review of a Confirmed Violation of 42 CFR 489.24 for Purposes of Assessing Civil Monetary Penalties or Excluding Physicians," (Exhibit 212). The QIO will provide the physician and hospital reasonable notice of it review, a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. (Instructions on notice of review and opportunity for discussion, and additional information that follow the regulatory requirements in 42 CFR 489.24(h) are found in §§9100-9150 of the QIO Manual.)

The RO is responsible for providing the QIO with all information relevant to the case that is within its possession and control. The RO sends the "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals," (Exhibit 138) to capture this information. This outline is helpful for organizing the review of the medical record. The specialty of the reviewing physician should be matched to the specialty of the physician who attended the patient and/or the individual's medical condition. If a physician did not see the patient, the RO uses the diagnosis of the patient or the usual physician assignment practice of the facility to determine the specialty of the physician reviewer.

Within 60 calendar days of receiving the case, the QIO must submit to the OIG a report on its findings and provide the RO with a copy of those findings. The report will provide an expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there are any medical utilization or quality of care issues involved in the case. The RO provides copies of the QIO report to the affected physician and/or hospital, if requested.

When there was no screening examination or when a delay would jeopardize the health or safety of individuals, QIO review is not required before the OIG may impose CMPs or exclude a physician from the Medicare program. In addition, if the QIO determines, after a preliminary review, that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, the QIO may, as its discretion, return the case to the RO with its opinion documented.

## 5370B - Releasing QIO Assessment

**(Rev. 1, 05-21-04)**

Upon request, the RO may release QIO assessment(s) to the physician and/or hospital or the affected individual, or his/her representative. The QIO physician's identity is confidential unless he/she consents to its release. The QIO review may be released pursuant to the requirements of 42 CFR 476.132 and 476.133.

## 5400 - Additional Provisions for the Investigation of Complaints in Nursing Homes

**(Rev. 1, 05-21-04)**

**SOM 7700**

**NOTE:** Sections 5000 to 5040 supersede §§5400 through 5460, where inconsistencies may exist.

The survey agency must review all complaint allegations and conduct a standard or an abbreviated standard survey to investigate complaints of violations of requirements if its review of the allegation concludes that:

- A deficiency in one or more of the requirements may have occurred;
- Only a survey can determine whether a deficiency or deficiencies exist; and
- The complaint is general or specific and may involve staff, residents, volunteers, the physical environment or administration.

Complaint investigations follow, as appropriate, the pertinent survey tasks, and information gathered is recorded on the appropriate survey worksheets. However, if the documentation required is minimal, use the Form CMS-807 to record information during the complaint investigation. Record deficiencies on the Form CMS-2567, the "Notice of Isolated Deficiencies," or both as applicable.

The survey agency does not conduct a survey if the complaint raises issues that are outside the purview of Federal participation requirements.

The timing, scope, duration and conduct of a complaint investigation are at the discretion of the State survey agency, except when the complaint involves an allegation of immediate jeopardy to resident health and safety, which must be investigated within 2 working days of receipt. In cases where the SA makes the determination that a higher level of harm is present, the investigation is to be initiated within 10 days of its receipt. The team should conduct the necessary investigation to resolve the complaint. If the complaint concerns conditions on a certain day (e.g., on weekends), or on a certain shift

(e.g., 11 p.m. - 7 a.m.), the survey agency should make an attempt to investigate it at the time relevant to the complaint. In most cases, the following tasks, or portion of tasks, should be performed in a complaint investigation:

If necessary, a specialized team may be used to investigate complaints. Team members may include, but are not limited to, an attorney, auditor, and appropriate health professionals. The specialized team is not necessarily composed of qualified surveyors. However, specialized team members provide unique talents and expertise that assist at least one qualified surveyor in identifying, gathering, and preserving documented evidence. Further information regarding the composition of the survey team is provided in Chapter 7.

## 5410 - Task 1: Offsite Survey Preparation

**(Rev. 1, 05-21-04)**

Obtain as much information as possible about the complaint before beginning to plan the investigation, including:

a. Name of complainant;

b. Nature of the complaint - describe exactly the facts of the complaint situation;

c. Information about when the complaint situation occurred, whether it was an isolated event or an ongoing situation - date, time, time between different events;

d. Place where the incident happened - care unit, resident room;

e. How it happened - sequence of events;

f. Whether a resident or a family member of a resident was involved;

g. Witnesses to complaint situation - anyone who saw incident happen;

h. Staff or other residents involved; and

i. Other persons involved - volunteers or visitors.

Review any information about the facility that would be helpful to know in planning the investigation. Contact the ombudsman to discuss the nature of the complaint and whether there have been any similar complaints reported to and substantiated by the ombudsman.

Review the related regulatory requirements or standards that pertain to the complaint. For example, if it is a complaint about abuse, review the requirements at 42 CFR 483.13.

Plan the investigation. Before going to the facility, plan what information is needed to obtain during the complaint investigation based on the information already acquired. Consider practical methods to obtain that information.

## 5420 - Task 2: Entrance Conference/Onsite Preparatory Activities

**(Rev. 1, 05-21-04)**

Onsite complaint investigations should always be unannounced. Upon entrance, advise the facility's Administrator of the general purpose of the visit. It is important to let the facility know why you are there, but protect the confidentiality of those involved in the complaint. Do not release information that will cause opportunities to be lost for pertinent observations, interviews, and record reviews required for a thorough investigation. For example, if the complaint is that food that is intended to be served hot is always served cold, do not tell the facility the exact complaint. Rather, tell them it is a situation related to dietary requirements.

## 5430 - Task 5: Information Gathering

**(Rev. 1, 05-21-04)**

The order and manner in which information is gathered will depend on the type of complaint that is being investigated. Conduct comprehensive, focused, and/or closed record reviews as appropriate for the type of complaint. It is very important to remember that the determination of whether the complaint happened is not enough. The surveyor needs to determine noncompliant facility practices related to the complaint situation and which, if any, requirements are not met by the facility.

Perform information gathering in order of priorities, i.e., obtain the most critical information first. Based on this critical information about the incident, determine what other information to obtain in the investigation.

Observations, record review and interviews can be done in any order necessary. As information is obtained, use what has been learned to determine what needs to be clarified or verified as the investigation continues.

Observe the physical environment, situations, procedures, patterns of care, delivery of services to residents, and interactions related to the complaint. Also, if necessary, observe other residents with the same care need. After determining what occurred, i.e., what happened to the resident and the outcome, investigate what facility practice(s) or procedures affected the occurrence of the incident.

**EXAMPLE**

It was verified through the investigation that a resident developed a pressure sore/ulcer which progressed to a Stage IV, became infected and resulted in the resident requiring

hospitalization for aggressive antibiotic therapy. Observe as appropriate: dressing changes, especially to any other residents with Stage III or IV pressure sores; infection control techniques such as hand washing, linen handling, and care of residents with infections; care given to prevent development of pressure sores (such as turning and repositioning, use of specialized bedding when appropriate, treatments done when ordered, keeping residents dry, and provision of adequate nutritional support for wound healing).

**Record review**: If a specific resident is involved, focus on the condition of the resident before and after the incident. If there are care issues, determine whether the appropriate assessments, care planning, implementation of care, and evaluations of the outcome of care have been done as specified by the regulatory requirements.

**EXAMPLE**

For a complaint of verbal and physical abuse, review the record to determine the resident's mood and demeanor before and after the alleged abuse. Determine if there are any other reasons for the change in the resident's demeanor and behavior. Determine whether an assessment has been done to determine the reason for the change in mood and behavior. Does the record document any unexplained bruises and/or complaints of pain, and whether they occurred in relation to the alleged incident?

Interviews: Interview the person who made the complaint. If the complainant is not at the facility at the time of the survey, he/she should be interviewed by telephone, if possible. Also, interview the person the complaint is about. Then, interview any other witnesses or staff involved. In order to maintain the confidentiality of witnesses, change the order of interviews if necessary. It may not always be desirable to interview the person who made the complaint first, as that may identify the person as the complainant to the facility. Interview residents with similar care needs at their convenience.

As interviews proceed, prepare outlines needed for other identified witnesses and revise outlines as new information is obtained.

## 5440 - Task 6: Information Analysis

**(Rev. 1, 05-21-04)**

Review all information collected. If there are inconsistencies, do additional data collection as needed, to resolve the inconsistencies. Determine if there is any other information still needed.

Determine whether:

- The complaint is substantiated;
- The facility failed to meet any of the regulatory requirements; and

- The facility practice or procedure that contributed to the complaint has been changed to achieve and/or maintain compliance.

## 5450 - Task 7: Exit Conference

**(Rev. 1, 05-21-04)**

Advise the Administrator of the complaint investigation findings and any present deficiencies. Do not inform him/her of confidential information unless the individual who provided the information specifically authorizes you to do so.

If a deficiency is not present now, but was present and has been corrected, notify the facility orally and in writing that the complaint was substantiated because deficiencies existed at the time that the complaint situation occurred. (See Appendix P, Task 5F, Section A and §7510 for specific information about imposing a CMP for egregious past noncompliance.)

If the complaint is unsubstantiated, i.e., the surveyor(s) cannot determine that it occurred and there is no indication of deficient practice, notify the facility of this decision.

Follow usual office procedure in notifying the resident and/or person who made the complaint of the findings.

## 5460 - Action on Complaints of Resident Neglect and Abuse, and Misappropriation of Resident Property

**(Rev. 1, 05-21-04)**

## 5460A - Written Procedures

**(Rev. 1, 05-21-04)**

The State must have written procedures in place to assure the timely (without undue delay) review and swift investigation of allegations of neglect and abuse, and misappropriation of resident property to protect residents from harm.

## 5460B - Review of Allegation

**(Rev. 1, 05-21-04)**

The State reviews all allegations of resident neglect and abuse and misappropriation of resident property regardless of the source of the complaint.

## 5460C - Investigating Allegations

**(Rev. 1, 05-21-04)**

The State investigates the allegation if oral or written evidence indicates that an individual employed by the facility could have neglected or abused a resident, or misappropriated a resident's property, or a deficiency in one or more requirements may have occurred. During the SA's investigation, it should evaluate how the facility developed policies and procedures to prevent the abuse, and after the abuse occurred, how the facility took action to report and investigate the allegations while ensuring the safety of the residents.

## 5460D - Factors Beyond Control of the Individual

**(Rev. 1, 05-21-04)**

The State must not make a finding that an individual neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

**EXAMPLE**: A nurse aide could not be found negligent for not providing clean bed and bath linens to a resident if the facility had no clean bed and bath linens available. However, the facility is responsible for providing clean bed and bath linens to residents.

## 5460E- Related Notification and Reporting Requirements

**(Rev. 1, 05-21-04)**

See Chapters 4 and 7 regarding notification and reporting requirements for findings of abuse, neglect, and misappropriation of resident property.

## 5500 - Complaints Involving Unaccredited Laboratories

**(Rev. 1, 05-21-04)**

**SOM 6136**

**NOTE:** This section applies to complaints against laboratories that hold a CLIA certificate of compliance, certificate of waiver (COW), and certificate of PPM (See §§5540-5590 for complaints regarding accredited laboratories).

A complaint is an allegation that could result in citing noncompliance with CLIA requirements. A complaint may be substantiated or unsubstantiated as a result of an investigation or survey. A substantiated complaint is one resulting in a finding of noncompliance at the time of the investigation, or a finding that noncompliance was proven to exist, but was corrected prior to the investigation. An unsubstantiated

complaint is an allegation where sufficient evidence could not be found to conclude that noncompliance with CLIA requirements existed during the investigation or at the time of the alleged violation. A complaint may be received in either the SA or the RO. The receiving organization should follow the procedures outlined below.

The SA obtains the following information for every complaint:

- Complainant's name, address, and telephone number, unless the complainant requests anonymity;
- Laboratory's name and address; and
- Description of problem, (e.g., personnel, places, and dates of occurrence).

## 5500A - Control

**(Rev. 1, 05-21-04)**

The SA establishes a file for the complaint and logs the action in a control system. The system may be manual or automated, but must facilitate tracking and control of the complaint.

## 5500B - Acknowledgment

**(Rev. 1, 05-21-04)**

If the complainant is known, the SA promptly issues written acknowledgment that the complaint is being investigated. The SA should not delay acknowledgment pending an investigation unless the investigation will take place within three working days. The SA must take appropriate precautions to protect the complainant's anonymity and privacy. The SA maintains a copy or record of the notification with the complaint documentation.

## 5500C - Evaluation

**(Rev. 1, 05-21-04)**

The SA evaluates any complaint to determine whether it should be investigated by the SA, or whether it should be forwarded to the RO for investigation or referral to the appropriate authority (e.g., OCR, OSHA, RO). The SA assesses the complaint to determine if an immediate survey is necessary. While the SA will perform most complaint surveys, complaints involving State-operated facilities are the responsibility of the RO. When the SA does not have jurisdiction, it should forward the complaint to the RO within three working days. If referral is not necessary, the SA considers whether or not any special notification is appropriate.

If a complaint is especially significant, sensitive, or attracting broad public or media attention, the SA informs the RO immediately.

## 5500D - Scheduling Investigations

**(Rev. 1, 05-21-04)**

The SA investigates within two working days of receiving the complaint and focuses on the specific problem area if the complaint involves possible immediate jeopardy to patient health and safety. Otherwise, the SA follows procedures for prioritizing and investigating certification-related complaints. Laboratories with complaints pending are identified and given priority in scheduling of regular certification surveys.

## 5500E - Conducting Investigations

**(Rev. 1, 05-21-04)**

The SA investigates complaints by means of an onsite survey, by telephone, by electronic communication, by letter, or by a documentary review. Complaint investigations are unannounced.

For onsite complaint investigations, the SA performs a full or partial survey based on the allegations. If a complaint alleges generalized inappropriate laboratory practices, the SA evaluates compliance with applicable requirements or conducts a full survey, as needed. If the complaint is of a specific nature, the SA performs a survey focused on areas relevant to the complaint.

## 5500F - Conducting Investigations in a Laboratory with a Certificate of Waiver

**(Rev. 1, 05-21-04)**

The RO authorizes an unannounced complaint survey of a laboratory holding a certificate of waiver only if it is based on a substantial allegation of noncompliance. The fact that a deficiency is not at the Condition-level does not preclude taking adverse action based on provisions contained in 42 CFR 493.1840. As with other laboratories, the SA investigates complaints made against laboratories with a certificate of waiver by means of an onsite survey, by telephone, letter, or by a review of documents.

The SA performs the onsite investigation based on the allegation and determines whether a laboratory is performing only waived tests and if the laboratory is following the manufacturer's instructions for performing the tests (See Appendix C).

## 5500G - Conducting Investigations in a Laboratory with a Certificate for PPM Procedures

**(Rev. 1, 05-21-04)**

The RO authorizes an unannounced complaint survey of a laboratory holding a certificate for PPM procedures only if based on a substantial allegation of noncompliance. This survey should not differ from a complaint survey done in any other laboratory performing non-waived testing, as all requirements for moderate complexity apply except routine survey.

Substantial indication that a laboratory is performing tests that do not appear on the PPM procedures test list; e.g., through billing procedures, should prompt a complaint survey of a certificate for PPM procedures laboratory followed by either proper registration or appropriate sanctions.

## 5500H - Post Investigation Actions

**(Rev. 1, 05-21-04)**

Following the investigation, the SA records any deficiencies on a Form CMS-2567 and provides it to the facility using regular procedures. Subsequent actions depend on the severity and nature of the deficiencies cited and the facility's willingness or ability to correct them.

When deficiencies are identified, the SA initiates actions as follows:

1. **Condition-Level Deficiencies - Immediate Jeopardy** - Certifies noncompliance and initiates procedures to recommend imposing alternative and principal sanctions.

2. **Condition-Level Deficiencies - No Immediate Jeopardy; Facility Provides an Acceptable POC** - Certifies noncompliance and initiates procedures to recommend imposing alternative sanctions based on the severity and nature of the deficiencies found.

3. **Lower Level Deficiencies - Facility Provides an Acceptable POC** - Certifies compliance based upon an acceptable POC and assembles documentation for RO review.

4. **Lower Level Deficiencies - Facility Unable or Unwilling to Provide Acceptable POC** - A facility with deficiencies may not participate without an acceptable POC. The SA recommends sanction action to the RO.

When no deficiencies are identified, no certification action is required.

## 5500I - Resolution/Closeout

**(Rev. 1, 05-21-04)**

**1 - Unsubstantiated**

The SA enters the unsubstantiated complaint into ACTS and documents the facility's certification file.

**2 - Substantiated**

The SA reports substantiated complaints using the Form CMS-2567 and any appropriate supporting documentation. The SA logs summary information in the control system and files a copy of the complaint documents in the facility's certification file. The SA enters complaints into ACTS. The laboratory will be charged a fee to cover the cost of the survey if noncompliance is documented.

The SA closes out all complaints with a follow-up notice to the complainant with the findings and disposition of the complaint. The SA should send this notice soon after the investigation and retains a copy with the complaint record.

The SA provides follow-up reports, as necessary, to any other appropriate parties such as the State Medicaid agency and/or initial referring agencies. The SA must be sure to protect the anonymity and privacy of the complainant.

The SA inputs the investigation information into ACTS within 45 days of the completion of the complaint survey.

## 5510 - CLIA-Exempt Laboratory Complaint Investigations - General

**(Rev. 1, 05-21-04)**

**SOM 6220**

A substantial allegation of noncompliance refers to a complaint from any of a variety of sources including complaints submitted in person, by telephone, through written correspondence, or in media. If the complaint were substantiated, it would have an impact on the health and safety of the general public or of individuals served by a laboratory as well as raise doubts as to a laboratory's compliance with one or more CLIA requirements.

## 5520 - Review of CLIA-Exempt Laboratory Complaints

**(Rev. 1, 05-21-04)**

**SOM 6222**

If the RO receives a complaint against a CLIA-exempt laboratory, the RO determines what action is appropriate. The RO may do the following;

- Send the information to the approved State for their action;
- Conduct a survey (full or partial); or
- Investigate the complaint during the course of the validation survey (full survey), if it is conducted within 90 days of the laboratory's licensure survey.

**NOTE:** Transfusion-related fatality investigations must be conducted by the RO. They may not be delegated to the approved State; however, the approved State may accompany the RO on the investigation. Where State laws apply to transfusion-related incidents, the approved State program should follow its established procedures and coordinate with the RO.

The RO reviews the approved State program's complaint activities as part of the overall annual review. The RO has the discretion to maintain or not maintain its own tracking system of complaints forwarded to the approved State program, depending on the information needed by the RO to perform the annual review.

If the approved State program receives a complaint against a CLIA-exempt laboratory, the approved State program determines what action is appropriate. If the approved State sanctions a CLIA-exempt laboratory in any way (e.g., the licensure is withdrawn), it must notify the RO.

## 5530 - Conducting Complaint Survey for CLIA-Exempt Laboratories

**(Rev. 1, 05-21-04)**

**SOM 6224**

The RO will complete the "Medicare/Medicaid/CLIA Complaint Form," Form CMS-562, for every complaint investigation it performs in a CLIA-exempt laboratory. When an investigation can be conducted via telephone (e.g., personnel credentials), the RO should do so. The RO obtains the following information for every allegation:

- Complainant's name and address, unless complainant requests anonymity. Do not disclose the identity of the complainant to the laboratory;

- Laboratory's name and address; and

- Description of problem, involving names, places, and dates.

The RO follows the same procedures for control and acknowledgement indicated in §5500. The RO will investigate all complaints within 2 days of receipt, if it determines that the complaint involves a potential immediate jeopardy to the individuals served by the laboratory or that of the general public. Otherwise, the RO investigates non-immediate jeopardy complaints within 45 days by survey, phone, etc. All complaint surveys are unannounced.

If a laboratory representative refuses to permit a complaint survey, the RO contacts the State and requests that it contact the laboratory to explain the protocol and, if necessary, suggest that the State take enforcement action against the CLIA-exempt laboratory. The RO conducts the complaint survey in accordance with the survey protocol and uses the appropriate survey forms specified in Exhibit 63 and the outcome-oriented protocol found in Appendix C.

Initially, the RO focuses the survey **only** on the Condition(s) or requirement(s) related to the complaint area(s). If the complaint is substantiated or if additional deficiencies are found during the course of the investigation, the RO expands the scope of the survey to include additional standards, conditions, and other CLIA requirements. If the complaint is not substantiated, the RO notifies the laboratory that it is in compliance with the CLIA condition (Exhibit 243). The RO also notifies the approved State program of the Condition-level compliance (Exhibit 244).

At the exit conference, the RO informs the laboratory of the deficiencies found. If the deficiencies pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the RO notifies the approved State program and the laboratory within two days by overnight mail and includes a copy of the Form CMS-2567. The RO directs the State program to take the appropriate enforcement action. (See Exhibits 231 and 228). The RO should follow-up with the State program within 15 days of its notification to the laboratory to verify that the recommended enforcement action has either been taken against the laboratory or that the laboratory has achieved compliance with CLIA requirements.

If, within 23 days of the RO's notification to them, the State program fails to take the appropriate enforcement action in cases where it has been determined that the operations of the laboratory pose an immediate jeopardy to public health, a temporary injunction or restraining order may be sought and granted without bond, pending issuance of a final order. The RO refers the case to the General Counsel within its region and requests that a suit be filed in United States District Court for the district in which the laboratory is located to enjoin continuation of the specific activity that is causing the hazard, or to enjoin the continued operation of the laboratory. See Exhibits 229 and 230.

If the deficiencies do not pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the RO prepares a Form CMS-2567 and forwards a letter along with the Form CMS-2567 to the laboratory within 10 days of completing the survey. The RO advises the laboratory that the State program is responsible for taking any enforcement action, if necessary, and monitoring the correction of the deficiencies and that the State will provide a report to the RO. (See Exhibit 231.) The RO informs the laboratory that the results of the survey will be made available to the public in accordance with the Federal Freedom of Information Act (FOIA) disclosure provisions.

Also, within 10 days after completing the survey, the RO notifies the State program in writing, of the laboratory's deficiencies. If necessary, the RO requests that the State obtain an acceptable POC and forward it to the RO. The RO directs the State to take the appropriate enforcement action, if necessary, and to report the action taken to the RO. See Exhibit 228.

The RO completes a Survey Team Composition and Workload Report, Form CMS-670, for all complaint surveys. Any subsequent revisits resulting from a complaint investigation that are conducted should not be documented on the Form CMS-670.

If an approved State program fails to take appropriate enforcement action in no-immediate-jeopardy situations, the RO documents its files accordingly and notifies CO. Failure to take and document the necessary enforcement action may subsequently jeopardize current or future approval of the State's laboratory licensure program.

## 5540 - Complaint Investigations and Surveys of Accredited Laboratories Under CLIA

**(Rev. 1, 05-21-04)**

**SOM 6174**

The statutory basis for conducting surveys of accredited laboratories on the basis of allegations of noncompliance is found in §353(e)(2)(D) of the Public Health Services Act (PHSA). A substantial allegation of noncompliance refers to a complaint from any of a variety of sources, including complaints submitted in person, by telephone, through written correspondence, or in media articles that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory, and that raises doubts as to a laboratory's compliance with one or more CLIA Conditions and/or requirements.

Complaints may be verbal, written or electronically received. Every effort should be made to secure a written form of the complaint, while maintaining anonymity, if requested. All complaint surveys are unannounced and conducted according to outcome-oriented survey principles (See Appendix C).

Complaints are investigated if they meet the following criteria:

- If substantiated, would have an impact on the health and safety of the general public or individuals served by the laboratory; and

- Would raise doubt as to the laboratory's compliance with one or more CLIA Conditions and/or requirements.

If the SA receives a substantial allegation of noncompliance directly from a complainant about an accredited laboratory, it acknowledges receipt of the complaint and advises the complainant that it is being forwarded to the RO for action. The SA forwards a copy of the acknowledgment letter and the complaint to the RO.

If the complaint is received directly by the RO, the RO will send a letter to the complainant acknowledging the complaint and advising the complainant of the intended course of action, and subsequently the results of any investigation, if appropriate, and of the corrective action taken. The RO evaluates the complaint and has the discretion to determine the course of action. The RO determines whether the RO, the SA, or the accreditation organization will investigate the complaint. If the RO determines that the accreditation organization should carry out its own investigation, Form CMS-2878A (Accredited Laboratory Allegation Report) is completed by the RO and a copy is sent to the accreditation organization for action. The RO should request to be notified of the results of any investigative action taken.

**NOTE:** Transfusion-related fatality investigations must be conducted by the RO or SA. Transfusion-related fatality investigations must not be referred to an accreditation organization for action.

If a complaint is received, and a CLIA survey can be completed within 90 days of the accreditation organization's inspection, the RO may authorize the SA to perform a full survey, i.e. all specialties and subspecialties covered by the certificate, and count it as a survey in the SA's validation workload.

## 5550 - RO Direction of Complaint Investigation of an Accredited Laboratory

**(Rev. 1, 05-21-04)**

**SOM 6176**

If the RO determines that a survey should be performed, the RO prepares a "Request for Validation Survey of Laboratory, Form CMS-2802A," (See Exhibit 107), and a "Medicare/Medicaid/CLIA Complaint," Form CMS-562. The RO then forwards both forms to the SA with a copy of the allegation(s). When an investigation can be conducted by letter or by telephone, such as to check on personnel credentials, those means are to be used.

The SA investigates a complaint within two days of receiving it from the RO, if the RO determines that the complaint involves a potential immediate jeopardy to the individuals served by the laboratory, or that of the general public. Otherwise, the RO will direct the SA to investigate non-Immediate Jeopardy complaints within 45 days.

## 5560 - Conducting Complaint Survey of an Accredited Laboratory

**(Rev. 1, 05-21-04)**

**SOM 6178**

The SA will conduct an unannounced survey of an accredited laboratory based on the substantial allegation of noncompliance. The SA conducts the complaint survey in accordance with outcome-oriented principles (See Appendix C). The SA conducts a focused survey as instructed by the RO on Form CMS-2802A. If the SA finds additional deficiencies during the course of the complaint investigation, it may expand the scope of the survey with RO approval.

At the exit conference, the SA informs the laboratory director of the deficiencies found. If the deficiencies do not pose an immediate jeopardy to the health and safety of individuals served by a laboratory, or that of the general public, the SA prepares a Form CMS-2567 and requests that the laboratory submit a POC. The SA informs the laboratory that the Form CMS-2567 will be made available to the public under the disclosure of survey information provisions. The SA indicates to the laboratory that the "Statement of Deficiencies" (Form CMS-2567) will be forwarded to the laboratory within 10 working days and that the POC must be returned to the SA within 10 calendar days. Upon receipt of the survey information, the RO makes a determination of whether or not sanctions will be imposed against the laboratory. The SA does not monitor the correction of deficiencies unless requested to do so by the RO.

If the deficiencies pose an immediate jeopardy to the health and safety of individuals, the SA prepares the Form CMS-2567 and notifies the RO for immediate action. The SA forwards the Form CMS-2567 to the RO within 2 days following the finding of an immediate jeopardy situation. Based on the information forwarded, the RO determines the most appropriate sanction to impose against the laboratory.

## 5570 - Forwarding Investigation Report to RO

**(Rev. 1, 05-21-04)**

**SOM 6180**

For non-immediate jeopardy found, the SA will submit the appropriate information as specified in the List of Documents in the Certification Packet (See Exhibit 63) to the RO, or through an update to ACTS within 45 days of completing the survey and notifies the

RO of the entry. In cases where immediate jeopardy exists, the SA submits all the appropriate information specified in the List of Documents in the Certification Package (See Exhibit 63), to the RO within 2 calendar days.

If the laboratory chooses not to submit a POC when deficiencies are found, the SA reports any known information about the laboratory's efforts to correct deficiencies.

## 5580 - Accredited Laboratory Found in Compliance Following a Complaint Survey

**(Rev. 1, 05-21-04)**

**SOM 6182**

If, after review of the documentation, the RO determines that the accredited laboratory is in Condition-level compliance with all CLIA requirements, it officially notifies the laboratory and forwards a copy of this letter to the SA and the accreditation organization. This letter advises that the accreditation organization may contact the laboratory about correcting any deficiencies below Condition-level.

## 5590 - Accredited Laboratory Found Not in Compliance Following a Complaint Survey

**(Rev. 1, 05-21-04)**

**SOM 6184**

If there are deficiencies that pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the laboratory may be subject to sanctions by the RO. Should the immediate jeopardy situation be corrected before the adverse action is taken or completed, the SA will advise the laboratory that it will revisit it to inspect all remaining Conditions.

If the RO determines that the laboratory is out of compliance with one or more Conditions, but they do not pose an immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, the RO notifies the laboratory that it is out of compliance and has been placed under SA monitoring jurisdiction (See Exhibit 241). A copy of the letter is provided to the accreditation organization.

The laboratory continues to be accredited by its accreditation organization and retains its CLIA certificate of accreditation during this monitoring period. The laboratory, however, becomes subject to the same requirements and survey and enforcement procedures applied to non-accredited laboratories found out of compliance following a survey. The laboratory is monitored until it reaches Condition-level compliance or its certificate of accreditation is revoked.

# Attachment 1 - Guidance to Distinguish Between the Priorities of Immediate Jeopardy and Non-Immediate Jeopardy-High in Nursing Home Allegations

**(Rev. 1, 05-21-04)**

## GUIDANCE TO DISTINGUISH BETWEEN THE PRIORITIES OF IMMEDIATE JEOPARDY AND NON-IMMEDIATE JEOPARDY-HIGH IN NURSING HOME ALLEGATIONS

*(The following scenarios are intended only to assist in the triage of certain allegations of noncompliance in a nursing home. Each situation is unique, and the following examples should be considered as guidance only. An additional resource is Appendix Q (Guidelines for Determining Immediate Jeopardy) of the State Operations Manual.)*

### 1. Allegations of abuse

- **Unexplained, unexpected death, with circumstances indicating that there was abuse or neglect** - A report of abuse/neglect resulting in an unexplained or unexpected death would not be triaged as immediate jeopardy if it is clear that the abuse/neglect is not present and ongoing. Whether or not an alleged perpetrator is still present in the facility and has unsupervised interaction with residents would be a consideration in assessing the urgency for an onsite visit. Unless the intake information is sufficient to determine the conditions are not present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

- **Resident is physically abused - spitting/slapping/sticking with sharp object, pushing, pinching** - A higher level of actual harm would exist if the situation has caused harm that negatively impacts the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. The extent of the injuries, whether or not the alleged perpetrator is still present in the facility and has unsupervised interaction with the residents, the frequency and duration of the behavior as well as the facility history, recent complaint reports, deficiencies cited, and other available information should also be reviewed in making a decision regarding the triage of complaints alleging physical abuse. Unless the intake information is sufficient to determine the conditions are not present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

- **Sexual assault, sexual harassment and sexual coercion** - A report of sexual assault, sexual harassment or sexual coercion would not be triaged as immediate jeopardy if it is clear that the threat of sexual abuse is not present and ongoing. A higher level of actual harm would exist if the situation has caused harm that negatively impacts the resident's mental, physical and/or psychosocial status and

is of such consequence to the person's well being that a rapid response by the SA is indicated. Whether or not an alleged perpetrator is still present and has unsupervised interaction with the residents in the facility would be a consideration in assessing the urgency for an onsite visit. Unless the intake information is sufficient to determine the conditions are not present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

- **Verbal Abuse - Resident is intimidated/threatened** - A higher level of actual harm would exist if the situation has caused harm that negatively impacts the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. Possible indicators of a higher level of actual harm could include: the resident crying, fleeing, not want to leave their room, fearful, not participating in activities, communicating, etc.). The frequency and duration of the behavior, as well as the facility history, recent complaint reports, deficiencies cited, and other available information should also be reviewed in making a decision regarding the triage of intakes alleging verbal abuse. Whether or not an alleged perpetrator is still present in the facility and has unsupervised interaction with the residents would be a consideration in assessing the urgency for an onsite visit. Unless the intake information is sufficient to determine whether or not the conditions are present and ongoing, the complaint should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

**2. Falls resulting in fracture or serious injury**

A report of falls resulting in fracture would not be triaged as immediate jeopardy if it is clear that the conditions causing and/or contributing to the falls are not present and ongoing. If the intake information is not sufficient to determine whether or not the conditions are present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within 2 working days. A higher level of actual harm would exist if the situation has caused harm that negatively impacts on the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. Factors to consider would be whether or not falls are preventable (the cause of the fall was the result of something the facility did or failed to do) or non-preventable (the cause of the fall was not the result of something the facility did or failed to do). Unless the intake information is sufficient to determine whether or not the conditions are present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

**3. Inappropriate use of physical or chemical restraints resulting in serious injury**

A report of inappropriate use of restraints resulting in injury would not be triaged as immediate jeopardy if it is clear that the inappropriate use of restraints is not present and ongoing. If the intake information is not sufficient to determine whether or not the

conditions are present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days. A higher level of actual harm would exist if the situation has caused harm that negatively impacts the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. Unless the intake information is sufficient to determine whether or not the conditions are present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

**4. Inadequate staffing that negatively impacts resident health and safety**

A higher level of actual harm would exist if the situation has caused harm negatively impacting on the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. The intake would need to provide information about the nature and frequency of the problems created for residents by the inadequate staffing. Other information that could be used to triage the allegation of inadequate staff would be facility history, recent complaint reports, deficiencies cited, MDS data (falls, weight loss, etc). Allegations of inadequate staff should also be analyzed to assess whether or not the lack of staff poses a life safety code violation that places residents at risk. The source or sources of the allegations may impact on the classification of the complaint. Numerous complaints from multiple sources could elevate the priority for an investigation.

## Attachment 2 - ACTS Required Fields

**(Rev. 1, 05-21-04)**

### ACTS REQUIRED FIELDS

| *TAB* | *FIELD(s)* | *DEFINITION* |
|---|---|---|
| Intake | **Intake Type** | 1) *Complaint* - A *complaint* is a report made to the SA or RO by anyone other than the administrator or authorized official for a provider or supplier that alleges noncompliance with Federal and/or State laws and regulations.<br>2) *Incident* - An *incident* is an official notification to the SA or RO from a self-reporting provider or supplier (i.e., the administrator or authorized official for the provider or supplier), or from a separate agency that is providing information about a provider or supplier |
| | **Intake Subtype (for Complaints)** | *A. Federal COPs, CFCs, RFPs, EMTALA*: The allegation relates to noncompliance with the Federal condition(s) of participation (COPs), condition(s) for coverage (CFCs), requirement(s) for participation (RFPs), or EMTALA requirement(s). This would include allegations of noncompliance with Federal requirements only or both Federal and State requirements. **(SAs and ROs are required to enter these cases into ACTS.)**<br>B. State-only, licensure: The allegation is related to noncompliance with State licensure requirements only**. (SAs have the option to enter these cases into ACTS.**)<br>C. No State or Federal provider compliance issue involved: The allegation does not relate to noncompliance with Federal or State survey and certification requirements. **(SAs have the option to enter these cases into ACTS.)** |

| *TAB* | *FIELD(s)* | *DEFINITION* |
|---|---|---|
| | **Intake Subtype (for Incidents)** | A) *Federally required, entity-reported*: A provider or supplier is required by Federal law, regulation, or policy to report this type of incident, which includes the following:<br>a. 42 C.F.R. §482.13(f)- *Standard: Seclusion and restraint for behavior management.* The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)**<br>b. 42 C.F.R. §483.13- For skilled nursing facilities (SNFs) and nursing facilities (NFs), the facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported …to other officials in accordance with State law through established procedures (including to the State survey and certification agency). **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions**.)<br>B) *State-required, may result in Federal noncompliance, entity-reported*: A provider or supplier is required by State law, regulation, or policy to report this type of incident to the SA. This type of incident may result in noncompliance with a Federal condition(s) of participation, condition(s) for coverage, requirement(s) for participation, or EMTALA requirement(s). Therefore, the SA must follow its complaint policies and procedures to investigate incidents of this type. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)**<br>*C. State-required, all other, entity-reported*: A provider or supplier is required by State law, regulation, or policy to report this type of incident to the SA. This type of incident does not imply noncompliance with Federal conditions or requirements. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)**<br>*D. Reported by other agencies*: A separate agency or entity is required by State law, regulation, or policy to officially report this type of incident to the SA. Example: An investigative report from an outside agency. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)**<br>*E. None of the above:* A provider or supplier is not required by Federal or State laws, regulations, or policies to report this type of incident. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)** |
| | **Complainant's Name** | For an incident the name of the official reporting the information is entered. |
| | **Source** | *A selection is made from a predefined list. The user cannot select more than 3.* |
| | **Received Dates: Start/End** | *Start Date:* The date of the telephone call or electronic correspondence; or, the date stamped by the SA or RO receiving office of the written correspondence.<br>*End Date:* The date the SA or RO has sufficient information to prioritize the complaint or incident. This is the date in which the SA or RO determines 1) whether an onsite survey to assess Federal compliance or further action is necessary and 2) the appropriate time frame for investigation. |

| *TAB* | *FIELD(s)* | *DEFINITION* |
|---|---|---|
| | **Priority** | *At least one priority must be selected for each intake. Some combinations are not permitted.*<br>A) *Immediate Jeopardy*: Intakes assigned this priority indicate immediate corrective action is necessary because a provider's or supplier's noncompliance with one or more conditions or requirements may have caused, or is likely to cause, serious injury, harm, impairment or death to a resident, patient or client.<br>B) *Non-Immediate Jeopardy - High*: Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions may have caused harm negatively impacting on the individual's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. This level of complaint is represented by specific rather than general information, such as, descriptive identifiers, individual names, date/time/location of occurrence, description of harm, etc.<br>C) *Non-Immediate Jeopardy - Medium*: Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions has caused or may cause harm that is of limited consequence and does not significantly impair the individual's mental, physical and/or psychosocial status to function.<br>D) *Non-Immediate Jeopardy - Low*: Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage. An onsite investigation may not be scheduled but the allegation would be reviewed at the next scheduled onsite survey, at the latest.<br>E) *Administrative Review/Offsite Investigation*: This priority is used for complaints/incidents that are triaged as not needing an onsite investigation. However, further investigative action (written/verbal communication or documentation) initiated by the SA or RO to the provider may be needed to ensure compliance with the Federal requirements. The additional information is adequate in scope and depth to determine that an onsite investigation is not necessary; however, a SA has the discretion to review the information at the next onsite survey.<br>F) *Referral - Immediate*: Complaints/incidents are assigned this priority if the seriousness of a complaint/incident and/or State procedures requires referral or reporting to another agency, board or network immediately for investigation.<br>G) *Referral - Other*: Complaints/incidents assigned this priority indicate referral to another agency, board, or network for investigation or for informational purposes.<br>H) *No action necessary*: Adequate information has been received about the complaint/incident such that the SA can determine with certainty that no further investigation, analysis, or action is necessary. For all cases except EMTALA, that do not allege immediate jeopardy, and at the SAs discretion an intake may not require a new onsite investigation if, at a previously completed survey, the same events were investigated; the previously completed survey evaluated the appropriate individuals, including those identified in the intake; and the situation did not worsen. These types of intakes should be linked to the appropriate survey that has already reviewed the issue. |
| | **Investigate Within X Days** | *Completion is required if the Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A - D).*<br>*A numerical time frame in calendar days is entered to support the Priority selected. The calendar date of the intake is counted as day zero.* |

| *TAB* | *FIELD(s)* | *DEFINITION* |
|---|---|---|
| | **Investigation Due By** | *Completion is required if the Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A - D).*<br>*A corresponding calendar date is entered.* |
| Allegations | **Allegation Category** | *At least one allegation category from a predefined list per intake is required unless Priority H - No Action Necessary is selected.* |
| | **Findings (Substantiated)** | A *substantiated* allegation is an allegation that did occur and is verified by evidence. An allegation is considered substantiated based on the finding about the individual or specific situation named by the complainant in his or her allegation; or, other residents or patients reviewed or similar situations, even if the noncompliance was corrected for the specific individual(s) named by the complainant in the allegation.<br>A. *Federal deficiencies related to the allegation are cited*<br>For nursing homes only, when Tag F698 is cited on the CMS-2567 for egregious past noncompliance between two periods of compliance for which a civil money penalty was imposed, ACTS automatically generates a check in the PNC (past noncompliance) box located at the Actions/Close tab.<br>B. *State deficiencies related to the allegation are cited*<br>C. *No deficiencies related to the allegation are cited*<br>The SA determined that the allegation did occur. However, at the time of the investigation, the provider had taken action necessary to prevent the deficient practice, and/or the allegation was not serious enough to warrant citing deficiencies. (This is not applicable for EMTALA, for EMTALA see the State Operations Manual at §3410.)<br>D. *Referral to appropriate agency*<br>After investigation, the complaint/incident was forwarded to the appropriate agency. |
| | **Findings (Unsubstantiated)** | An unsubstantiated allegation is an allegation where evidence cannot support that the allegation did occur.<br>*A. Allegation did not occur*<br>Evidence indicates that the allegation did not occur.<br>*B. Lack of sufficient evidence*<br>The SA is unable to verify that the allegation did occur because of insufficient evidence. The evidence is inconclusive.<br>*C. Referral to appropriate agency*<br>After investigation, the complaint/incident was referred to the appropriate agency. |
| | **Priority** | *This field is shared with Intake page and Deemed page (when applicable).* |
| | **Investigate Within X Days** | *This field is shared with Intake page and Deemed page (when applicable).* |
| | **Investigation Due By** | *This field is shared with Intake page and Deemed page (when applicable).* |

| *TAB* | *FIELD(s)* | *DEFINITION* |
|---|---|---|
| | **Death Associated with Restraint/ Seclusion [Grid]** | *For Hospitals: When allegation type = Death Associated with Restraint/Seclusion (05), at least one row must be completed, except for Urban/Rural field.* |
| EMTALA (Fields required only if 'Create EMTALA Allegation' box is checked) | **EMTALA RO Response** | |
| | **EMTALA RO Response Date** | |
| | **Type of Emergency** | |
| | **RO EMTALA Determination** | |
| | **Resolution** | |
| | **RO Confirmed Violation Date** *or* **RO Confirmed No Violation Date** | *One of these fields should always be completed* |
| | **Type of Allegation** | |
| Deemed and Accredited (Fields enabled if 'Deemed for Medicare Participation' or 'Accredited' box is checked). | **Priority** | *This field is shared with Intake and Allegation pages.* |
| | **RO Response** | *There are no edits on these fields at this time.* |
| | **Regional Representative** | |
| | **Region** | |
| | **Date** | |
| Investigation | **Investigated By** | *Required when Complaint Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A - D)* |
| | **Investigation Completed** | *Required when Complaint Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A - D)*<br>The date that the result of the investigation is communicated to the provider or supplier. |

| *TAB* | *FIELD(s)* | *DEFINITION* |
|---|---|---|
| Actions/Close | **Forwarded to RO/MSA** | If the intake originates from the CMS RO, the SA should check the "Forwarded to CMS/MSA" box in all complaint/incident scenarios.<br>If the intake originates from the SA, SAs should not check the box or enter a date for all nursing home intakes.<br>For non-long-term care intakes, the SA should check the "Forwarded to RO/MSA" box on the complaint/incident record in the three following scenarios:<br>i. If the complaint/incident survey is on an accredited/deemed provider/supplier.<br>ii. If the complaint results in an EMTALA investigation.<br>iii. If the complaint/incident survey is on an "other than accredited/deemed provider or supplier" and the SA is recommending termination. |
| | **Proposed Action** | *At least one proposed action per complaint/incident record if a survey is present.* |
| | **Proposed Action Date** | ***Date of the notice sent to the provider/supplier informing the provider/supplier of actions that may be taken as a result of the investigation findings. If the provider/supplier is in compliance, the proposed action date is the date the provider/supplier is notified that it is in compliance.***<br>*At least one proposed action date per complaint/incident record if a survey is present.* |
| | **Overall Findings** | *Supplied by ACTS (For complaints, uses same rule as Findings: Required when Complaint Priority = Immediate Jeopardy or Non-immediate Jeopardy (Priorities A - D); for incidents, defaults on-screen to Not Applicable).* |
| | **Reason Closed** | Field is completed by selecting one or more of the following:<br>A. *Paperwork complete* - All information and documentation, including notification to the complainant, if applicable, related to this complaint or incident has been completed in the SA or RO file.<br>B. *Withdrawn* - The complainant contacted the entity receiving the allegation and asked that the allegation be removed.<br>C. *Referred* - At the intake, during administrative review, or after the onsite complaint survey, it is determined that the issues involved must be directed to another agency or organization for resolution.<br>D. *No jurisdiction* - The issues identified at intake, during an administrative review or after a survey do not involve Medicare/Medicaid participation requirements.<br>E. *Provider/Supplier Termination* - The provider or supplier has been terminated from participation in the Medicare and/or Medicaid programs. |
| | **Date Closed** | *Date associated with the latest reason closed action selected.* |

| *TAB* | *FIELD(s)* | *DEFINITION* |
|---|---|---|
| NOTIFICATION:<br><br>Notices Button (every tab) and the Acknowledgement and Parties Notified section on the Investigation Properties tab | | *At least one notification is required, except when Priority is No Action Necessary.* |